A Multi-Stakeholder Workshop of the
Joint EFGCP-MedTech Europe
Medical Technology Working Party on

Mitigating Risks in the Lifecycle of Medical Devices:

Options and Challenges in Building Clinical Evidence

4 December 2014 – The Hotel, Brussels, Belgium

Organised by the newly formed
Joint Medical Technology Working Party of

EFGCP
where science and ethics meet

MedTech Europe
from diagnosis to cure

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Introduction

The upcoming Regulation on Medical Devices will change the landscape for the development of medical devices in Europe but also in the current legislative framework there is room for improvement in mitigating risks in the clinical development and life cycle management of medical devices. This multi-stakeholder workshop of the newly formed joint EFGCP - MedTech Europe Medical Technology Working Party will offer the floor for an exchange of views, opinions and proposed solutions on ethical, safety and quality topics of particular complexity and concern in the current and upcoming medical device legislation amongst all stakeholders. For the first time, patient representatives, healthcare providers, ethicists, competent authorities, industry and politicians will be encouraged to present and discuss together the needs, options and opportunities for mitigating risks in the development and full life cycle of medical devices in a neutral multi-stakeholder forum. In this first workshop we will discuss the similarities and differences between the development of medicines and medical devices, areas of mutual learning about suitable procedures in clinical trials and overall development concepts in the interest of the patient, identify the key ethical and quality issues and particular practical questions to be worked out in more detail in subsequent workshops.

Programme Committee

Philippe Auclair	Abbott Laboratories, Belgium
John Brennan	Eucomed, Belgium
Hugh Davies	Health Research Authority, European Forum for Good Clinical Practice (EFGCP), United Kingdom
Nicky Dodsworth	Premier Research, European Forum for Good Clinical Practice (EFGCP), United Kingdom
Edel Fitzgerald	MedTech Europe, Belgium
Renate Heinisch	European Economic and Social Committee – BAGSO, Germany
Eric Klasen	Medtronic, Eucomed, Belgium
Ingrid Klingmann	Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
Benny Ons	Becton Dickinson International, Belgium
Dario Pirovano	Eucomed, Belgium
Laurène Souchet	European Patients' Forum (EPF), Belgium
Lynne Van Poelgeest	World Federation of Incontinent Patients (WFIP), The Netherlands

Faculty

Philippe Auclair	Abbott Laboratories, Belgium
Anna Chioti	CRP Santé, Luxembourg
Hugh Davies	Health Research Authority, European Forum for Good Clinical Practice (EFGCP), United Kingdom
Nicky Dodsworth	Premier Research, European Forum for Good Clinical Practice (EFGCP), United Kingdom
Yves Geysels	EFGCP, Quintiles, European Forum for Good Clinical Practice (EFGCP), Belgium
Eric Klasen	Medtronic, Eucomed, Belgium
Ingrid Klingmann	Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
Greet Musch	Federal Agency for Medicines and Health Products, Belgium
Edmund Neugebauer	University of Witten/Herdecke, Germany
Quentin Pankhurst	University College London, United Kingdom
Ernst Singer	Ethics Committee of the Medical University of Vienna, Austria
Lynne Van Poelgeest	World Federation of Incontinent Patients (WFIP), The Netherlands

Workshop Venue

The Hotel
Boulevard de Waterloo 38
1000 Brussels - Belgium
Tel: +32 2 504 11 11
Fax: +32 2 504 21 11
e-mail: book@thehotel.be
Website: http://www.thehotel-brussels.be

Workshop Language

The language of the workshop will be English.

Registration & Information

OPEN EVENT - E-mail conferences@efgcp.eu or visit www.efgcp.eu

Agenda

08:30 Registration & Welcome Coffee

09:00 Welcome, General Introduction & Aim of the Day
Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium & Eric Klasen, Medtronic, Eucomed, Belgium

09:10 Keynote presentation: Why is there a need to define ethical and quality conditions for clinical development of medical devices – Does one-size fit all?
Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium

SESSION 1 - CLINICAL DEVELOPMENT IN MEDICAL DEVICES AND MEDICINES: SIMILARITIES AND DIFFERENCES

09:30 Introduction to Medical Devices specificities
Eric Klasen, Medtronic, Eucomed, Belgium

10:00 OXFORD DEBATE on similarities and differences in the clinical development of medicines and medical devices

Motion A. "There are so many different aspects in the development of medicines and medical devices that different clinical principles and procedures need to be applied in the interest of the patient"

Panelist 1*: Philippe Auclair, Abbott Laboratories, Belgium*

Panelist 2*: Speaker invited*

Motion B. "The same principles and procedures for clinical development have to be applied in the interest of the patient"

Panelist 1: Speaker invited

Panelist 2: Edmund Neugebauer, University of Witten/Herdecke, Germany

11:00 *Coffee Break*

SESSION 2 - ETHICAL CONSIDERATIONS: WHEN ARE CLINICAL TRIALS NECESSARY?

Chairperson: *Yves Geysels, Quintiles, European Forum for Good Clinical Practice (EFGCP), Belgium*

11:30 What are ethical constraints for randomised clinical trials in medical device development?
Hugh Davies, Health Research Authority, European Forum for Good Clinical Practice (EFGCP), United Kingdom

12:00 What is a fair clinical pathway from innovation to research and to practice?
Quentin Pankhurst, University College London, United Kingdom

12:30 Open forum discussion

13:00 *Lunch*

SESSION 3 - QUALITY REQUIREMENTS

Chairperson: *Nicky Dodsworth, Premier Research, European Forum for Good Clinical Practice (EFGCP), United Kingdom*

14:00 Importance of quality outcomes: the role of training for investigators and patients
Speaker invited

14:30 The enhanced role of competent authorities and notified bodies for the quality outcomes
Speaker invited

15:00 *Coffee Break*

OPEN FORUM DISCUSSION & CONCLUSIONS

15:30 Open Forum Discussion: Lessons jointly learned and areas of potential solutions to be worked out in next workshops

Panelists:

Clinician: *Anna Chioti, CRP Santé, Luxembourg*
Competent Authority: *Greet Musch, Federal Agency for Medicines and Health Products, Belgium*
Ethics Committee: *Ernst Singer, Ethics Committee of the Medical University of Vienna, Austria*
Patient representative: *Lynne Van Poelgeest-Pomfret, World Federation for Incontinent Patients, The Netherlands*

Politician: *Speaker invited*
European Commission: *Speaker invited*
Industry: *Speaker invited*
Academia: *Speaker invited*

16:20 Conclusions & Next Steps

16:30 *Close*