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

www.efgcp.eu - conferences@efgcp.eu
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

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<th>Name</th>
<th>Organisation and Place</th>
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<td>Philippe Auclair</td>
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<td>Benny Ons</td>
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<td>Dario Pirovano</td>
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<td>Laurène Souchet</td>
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<td>Lynne Van Poelgeest</td>
<td>World Federation of Incontinent Patients (WFIP), The Netherlands</td>
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Faculty

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<td>Edmund Neugebauer</td>
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<td>Quentin Pankhurst</td>
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<td>Ernst Singer</td>
<td>Ethics Committee of the Medical University of Vienna, Austria</td>
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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