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

Establishing Best Practices in Clinical Development of In Vitro Diagnostics, Companion Diagnostics and Healthcare Apps: Barriers and Pathways to Success

7 & 8 May 2015 – Chamber of Commerce and Industry of Serbia, Belgrade, Serbia

Organised by the Joint Medical Technology Working Party of

In Partnership with

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Introduction

New regulations under consideration in the EU focus on new technologies such as novel in vitro diagnostics, companion diagnostics and on the development of healthcare apps, all of which rely on information to deliver positive health outcomes.

Gathering clinical evidence and knowing when and how to conduct clinical investigations for these new technologies is a challenge which still needs to be addressed.

This Joint EFGCP-MedTech Europe Working Party workshop will focus on the means to address these open questions and on the generation of clinical evidence for IVDs, companion diagnostics and healthcare apps, from the point of view of clinicians, patients, regulators and product developers.

Programme Committee

Anna Chioti  Luxembourg Institute of Health, Luxembourg
Maja Conkic  KLINIS Association, Axiom International, Serbia
Eric Klasen  Medtronic, Switzerland
Ingrid Klingmann  Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
Jesús Rueda Rodríguez  European Diagnostic Manufacturers Association (EDMA), Belgium
Luc Van Hove  Biocartis, Belgium

Faculty

Filippo Buccella  Parent Project, Italia
Ravi Chana  NIHR Office for Clinical Research Infrastructure (NOCRI), United Kingdom
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Damjan Damjanovic  MA, Serbian Patient Association, “Plavi Krug”, Serbia
Ivana Gadjanski  Fab Initiative, Pubsonic, TED, Center for Bioengineering – BioIR, Serbia
Stanimir Hasurdziev  Bulgarian National Patients Association, Bulgaria
Magdalena Kalata  European Diagnostic Manufacturers Association (EDMA), Belgium
Eric Klasen  Medtronic, Switzerland
Ingrid Klingmann  Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
Hugues Malonne  Faculté de Pharmacie, Université Libre de Bruxelles, Belgium
Sava Marinkovic  MySkin, USA
Peter Martin  Roche, Germany
Anastassia Negrouk  European Organisation for research and Treatment of Cancer (EORTC), Belgium
Sinisa Radulovic  Institute for Oncology and Radiology of Serbia, Serbia
Jesús Rueda Rodríguez  European Diagnostic Manufacturers Association (EDMA), Belgium
Fabien Roy  Hogan Lovells International LLP, Belgium
Zoran Todorovic  School of Medicine of University of Belgrade, Bioethical Society of Serbia, Serbia
Luc Van Hove  Biocartis, Belgium
Lynne Van Poelgeest  Federation of Incontinent Patients (WFIP), The Netherlands

Workshop Venue

Chamber of Commerce and Industry of Serbia
Resavska 13-15
11000 Belgrade, Serbia
Tel.: +381 (0)11 3300 900 - Fax: +381 (0)11 3230 949
Workshop Language

The language of the workshop will be English.

Registration & Information

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Agenda
7 May 2015

08:15 Registration & Welcome Coffee

08:45 Welcome, General Introduction & Aim of the Day

Maja Conkic, President at Association for Advancement of Clinical Research of Serbia KLINIS; Jesus Rueda, Director International Affairs, EDMA and Anna Chioti, Head of Clinic CIEC, Luxembourg Institute of Health.

PLENARY SESSION 1: SETTING THE SCENE

Chairperson: Luc Van Hove, Biocartis, Belgium
Co-Chair: Lynne Van Poelgeest World Federation of Incontinent Patients (WFIP), The Netherlands

09:00 Current Strategies and Challenges in Clinical Development of IVDs
Luc van Hove, Biocartis, Belgium

09:30 Current Strategies and Challenges in Clinical Development of Companion Diagnostics
Speaker invited

10:00 Current Strategies and Challenges in Clinical Development of Healthcare Apps
Speaker invited

10:30 Questions & discussion

10:45 Coffee Break

BREAK-OUT SESSIONS 1, 2, 3: What are the Current barriers and Options?

11:00 Workshop 1: IVDs: Widen the view of participants to find an approach of the challenge that has every preference in it
Chair: Luc Van Hove, Biocartis, Belgium
Rapporteur: Ivana Gadjanski, Fab Initiative, Pubsonic, TED, Center for Bioengineering – BioIRC, Serbia

Workshop 2: Companion Diagnostics: Widen the view of participants to find an approach of the challenge that has every preference in it
Chair: Speaker invited
Rapporteur: Sinisa Radulovic, Institute for Oncology and Radiology of Serbia, Serbia

Workshop 3: Healthcare Apps: Widen the view of participants to find an approach of the challenge that has every preference in it
Chair: Speaker invited
Rapporteur: Filippo Buccella, Parent Project, Italia

12:45 Lunch Break
13:45 Feedback from Break-Out Groups by rapporteurs
   Chair: Anna Chioti, Luxembourg Institute of Health, Luxembourg
   Co-chair: Damjan Damjanovic, MA, Serbian Patient Association, “Plavi Krug”, Serbia
   - IVDs as an introduction (13:45)
   - Companion Diagnostics (14:00)
   - Healthcare Apps (14:15)

14:30 Open Forum Discussion on Results from the Break-out Groups

15:00 Coffee Break

PLENARY SESSION 2:
HOW TO OVERCOME THE BARRIERS IN CLINICAL DEVELOPMENT FOR IVDs, COMPANION DIAGNOSTICS AND HEALTHCARE APPS

Chairperson: Speaker invited

15:30 Keynote Industry View: Broad view on the future regulation regarding IVDs, Companion Diagnostics and Healthcare Apps
   Jesus Rueda Rodriguez, European Diagnostic Manufacturers Association (EDMA), Belgium

16:00 Keynote from Patient: Patient Perspective
   Stanimir Hasurdziev, Bulgarian National Patients Association, Bulgaria

16:30 Keynote Academia: Academic Perspective
   Anastassia Negrouk, European Organisation for research and Treatment of Cancer (EORTC), Belgium

17:00 Summary of the key lessons learnt
   Jesus Rueda Rodriguez, European Diagnostic Manufacturers Association (EDMA), Belgium

17:30 End of Day 1

18:30 Social Event
   Visit to Nikola Tesla Museum, Dinner at Kalemegdanska Terasa Restaurant
8 May 2015

08:30 Registration & Welcome Coffee

PLENARY SESSION 3
ETHICAL ISSUES IN CLINICAL STUDIES WITH IVDs, COMPANION DIAGNOSTICS AND HEALTHCARE APPS

Chairperson: Ingrid Klingmann, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
Co-Chair: Speaker invited

09:00 Fair Consent: What is this? Issue of transparency, secondary broad consent
Zoran Todorovic, School of Medicine of University of Belgrade, Bioethical Society of Serbia, Serbia

BREAK-OUT SESSIONS 4,5,6: Pathways to Success

10:00 Introduction: define what would be acceptable solutions and concrete recommendations to go in the future regulation for all present stakeholders
Peter Martin, Roche, Germany

10:30 Coffee Break

11:00 Workshop 4: IVDs
Chair: Ravi Chana, NIHR Office for Clinical Research Infrastructure (NOCRi), United Kingdom
Rapporteur: Magdalena Kalata, European Diagnostic Manufacturers Association (EDMA), Belgium

Workshop 5: Companion Diagnostics
Chair: Hugues Malonne, Faculté de Pharmacie, Université Libre de Bruxelles, Belgium
Rapporteur: Speaker invited

Workshop 6: Healthcare Apps
Chair: Sava Marinkovic, MySkin, USA
Rapporteur: An Cloet, MSD, Luxembourg

12:30 Lunch

13:30 Feedback from Break-Out Groups by rapporteurs
Chair: Maja Conkic, KLINIS Association, Axiom International, Serbia
- IVDs as an introduction (13:45)
- Companion Diagnostics (14:00)
- Healthcare Apps(14:15)
PLENARY SESSION 4
SOLUTIONS

Chairperson: Fabien Roy, Hogan Lovells International LLP, Belgium
Co-Chair: Eric Klasen, Medtronic, Switzerland

14:30
Panel Discussion on the Future EU Regulation
How could we implement/add in the future regulation what they heard during those two days, explaining what the future regulation will be about and what the future of clinical development for IVD, Companion Diagnostics and Healthcare Apps will look like.

Panelists:
Hugues Malonne, Faculté de Pharmacie, Université Libre de Bruxelles, Belgium

15:30
Open Forum Discussion
Panelists: Speakers invited

16:00
Conclusions and Next Steps

16:15
End of the workshop