Joint EFGCP-EFPIA Multi-Stakeholder Workshop on

Communicating Clinical Trial Results to Meet Public Needs

-Working towards Implementation of Lay Summaries-

2 May, 2017

Brussels, Belgium

Organised by:

EFGCP
where science and ethics meet

efpia

conferences@efgcp.eu - www.efgcp.eu

Introduction

This will be an interactive Workshop. After an introductory session on updating the audience the following sessions will consist of introductory presentations and pre-prepared, structured discussions with the audience.

In the feedback process the participants will receive an opportunity to make comments on all sections of the proposed EU Commission Guideline. The results will be provided to the Commission by EFGCP.

Programme Committee

Kerstin Breithaupt-Grögler	kbr, Clinical Pharmacology Services, Germany
Giulio Maria Corbelli	European AIDS Treatment Group (EATG), Italy
Solange Corriol-Rohou	AstraZeneca, France
Sini Eskola	European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
Kaisa Immonen	European Patients' Forum (EPF), Belgium
Angelika Joos	Merck Sharp & Dohme, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
Ingrid Klingmann	Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
Laurie Myers	Co-chair of the Multi-Regional Clinical Trials (MRCT) Center Return of Results initiative, Harvard University, Merck &Co,USA
Theo Raynor	University of Leeds, United Kingdom

Faculty

Kerstin Breithaupt-Grögler	kbr, Clinical Pharmacology Services, Germany
Juan Garcia Burgos	European Medicines Agency (EMA)
Giulio Maria Corbelli	European AIDS Treatment Group (EATG), Italy
Solange Corriol-Rohou	AstraZeneca, France
Sini Eskola	European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
Julie Holtzpole	AstraZeneca, USA
Amanda Hunn	Health Research Authority (HRA), United Kingdom
Kaisa Immonen	European Patients' Forum (EPF), Belgium
Angelika Joos	Merck Sharp & Dohme, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
Ingrid Klingmann	Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
David Leventhal	Pfizer, USA
Theo Raynor	University of Leeds, United Kingdom

Workshop Language

The language of the workshop will be English.

Workshop Venue

Crowne Plaza Le Palace

Rue Gineste 3
1210 Brussels, Belgium
Tel.: + 32 (0)2 203 62 00 – Fax.: +32 (0)2 203 55 55
Click here for the website

Registration & Information

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

Agenda

Tuesday 2nd May

08:15 *Registration & Welcome Coffee*

09:00 **Welcome, Introduction and Conclusions from Lay Summary Workshop in 2015**
***Ingrid Klingmann**, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium*

SESSION 1: What progress have we made?

Chairpersons: ***Sini Eskola,** European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium & **Kaisa Immonen**, European Patients' Forum (EPF), Belgium*

09:05 **The EU Commission's concept for these guidelines**
***Speaker invited**, European Commission*

Discussion

09:35 **Other current initiatives and efforts on European-American alignment in the Lay Summary concepts**
***Angelika Joos**, Merck Sharp & Dohme, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium*

Discussion

10:05 **Critical aspects, areas of difficult consensus, and expectations on the guidelines' impact**
***Amanda Hunn**, Health Research Authority (HRA), United Kingdom*

10:30 **Q & A**

10:40 *Coffee Break*

SESSION 2: What is a suitable Lay Summary?

Chairpersons: ***Kerstin Breithaupt-Grögler,** kbr, Clinical Pharmacology Services, Germany & **Giulio Maria Corbelli,** European AIDS Treatment Group (EATG), Italy*

11:00 **Statements and Panel Discussion on expectations for suitable Lay Summaries**

- What does make Lay Summaries attractive for different populations and stakeholders?
- What kind of accessibility is required (e.g., countries, languages, hard to reach populations, etc.)
- Use of modern technologies?

Panellists: ***Juan Garcia Burgos**, European Medicines Agency (EMA)*

12:30 *Lunch Break*

SESSION 3:Constructive proposals for implementing the Lay Summary production process in an organisation

Chairpersons: ***Solange Corriol-Rohou,*** *AstraZeneca, France &* ***Co-chair invited***

13:30 **Practical examples, experiences and plans from**
Julie Holtzpole*, AstraZeneca, USA*
Theo Raynor*, University of Leeds, United Kingdom*

- Required processes?
- Involvement of patients?
- Legal conditions?
- Costs?

14:30 **Discussion**

SESSION 4: How to prepare Europe for Lay Summaries?

15:15 **Panel and Open Forum Discussion**

Moderators: ***Angelika Joos****, Merck Sharp & Dohme, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium &* ***Co-chair invited***

- Training initiatives for Lay Summary producers?
- Making the public aware of availability of Lay Summaries?
- How to establish a continuous improvement system?

Panellists: ***Juan Garcia Burgos****, European Medicines Agency (EMA)*
Giulio Maria Corbelli, *European AIDS Treatment Group (EATG), Italy*
Kaisa Immonen, *European Patients' Forum (EPF), Belgium*
David Leventhal*, Pfizer, USA*
Theo Raynor*, University of Leeds, United Kingdom*

16:30 **Conclusions & Next steps**
Ingrid Klingmann*, Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium*

16:45 *End of Workshop*