EFGCP Multi-Stakeholder Workshop on

Communicating Clinical Trial Results to Meet Public Needs

- A Meaningful Future for Lay Summaries -

29 May 2015

Thon Hotel EU
Brussels, Belgium

Organised by:

EFGCP
where science and ethics meet

In Partnership with:

EATG European AIDS Treatment Group

EGAN Patients Network for Medical Research and Health

EPF European Patients Forum

MRCT Multi-Regional Clinical Trials
The MRCT Center at Harvard

efpia

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Introduction

Returning results of clinical trials to participants allows for investigators and sponsors to honor the essential contributions and voluntarism of study participants, while improving the transparency of those trials. There are two distinct options for making clinical trial results available in lay language: on an individual participant level through the study investigator or with a more general public approach by posting aggregate results onto a webpage. Both options provide opportunities and may also pose some practical challenges.

The second option for returning results is the actual focus of the new EU Clinical Trials Regulation adopted by European legislation makers in 2014. This revised framework will bring significant advances regarding available public information about clinical research and its results compared to today's situation. It will for the first time ensure that layperson summaries of all clinical trials will be published on an EU database, enabling trial participants to better understand the value of their contribution and increasing transparency for the general public.

We are now at a critical stage in the process where new rules have to be developed to implement legal requirements into daily practice. Pragmatic guidance needs to balance increased public information needs with seamless integration of new steps into global clinical research operations, while safeguarding the privacy of patients, preserving the scientific rigor and trust in the regulatory systems, and maintaining the incentives for investments into European biomedical research.

This workshop aims to facilitate a dialogue among stakeholders to understand the wishes and expectations of patients and share experience and best practices of sponsors. A common understanding of the opportunities and challenges of various options is essential to achieving a successful implementation of the new rules in a globalised research environment.

More concretely, basic principles and specific tools that are consistent with health literacy principles will be discussed to ensure the content of lay summaries is practical, relevant to patients, and understandable. In addition, the workshop will investigate how such summaries could best be communicated to ensure that they are reaching their intended audience to maximise their usefulness.

In summary, the discussion aims to help develop a vision and framework that addresses stakeholder needs while increasing transparency and value for public health.

Programme Committee

Brendan Barnes	European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
Mark Barnes	Multi-Regional Clinical Trials (MRCT) Center, Harvard University, Ropes & Gray LLP, USA
Barbara Bierer	Multi-Regional Clinical Trials (MRCT) Center, Harvard University, USA
Giulio Maria Corbelli	European AIDS Treatment Group (EATG), Italy
Sini Eskola	European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
Kaisa Immonen-Charalambous	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
Rebecca Li	Multi-Regional Clinical Trials (MRCT) Center, Harvard University, USA
Marianne Maman	Novartis Pharma, European Federation of Pharmaceutical Industries and Associations (EFPIA), Switzerland
Laurie Myers	Merck, USA
Cees Smit	European Genetic Alliances Network (EGAN) / Vereniging Samenwerkende Ouder- en Patiëntenorganisaties (VSOP), European Forum for Good Clinical Practice (EFGCP), The Netherlands

Faculty

Giulio Maria Corbelli	European AIDS Treatment Group (EATG), Italy
Jan Geissler	European Patients' Academy on Therapeutic Innovation (EUPATI), Germany

Angelika Joos	Merck Sharp & Dohme, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
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Ingrid Klingmann	Pharmaplex, European Forum for Good Clinical Practice (EFGCP), Belgium
Laurie Myers	Merck, USA
Sir Nick Partridge	Terrence Higgins Trust, United Kingdom
Solange Rohou	AstraZeneca, United Kingdom
Christoph Schuhmacher	European Clinical Research Infrastructure Network (ECRIN), France
Cees Smit	European Genetic Alliances Network (EGAN) / Vereniging Samenwerkende Ouder- en Patiëntenorganisaties (VSOP), European Forum for Good Clinical Practice (EFGCP), The Netherlands

Workshop Language

The language of the workshop will be English.

Workshop Venue

Thon Hotel EU
Rue de la Loi/Wetstraat 75
B-1040 Brussels - Belgium
Tel.: +32 (0)2 204 3911
E-mail: eu@thonhotels.be
Website: http://www.thonhotels.com/eu

Registration & Information

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

Agenda

Friday 29th May

08:15 Registration & Welcome Coffee / Posters Viewing

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

SESSION 1: The Big Picture on Return of Results to Patients

Chairperson: ***Kaisa Immonen-Charalambous**, European Patients' Forum (EPF), Belgium*

09:15 Keynote Patient's View: Sharing Clinical Trial Results - A Holistic Patient Approach
***Cees Smit**, European Genetic Alliances Network (EGAN) / Vereniging Samenwerkende Ouder- en Patiëntenorganisaties (VSOP), European Forum for Good Clinical Practice (EFGCP), The Netherlands*

09:35 Q&A

09:45 Keynote Industry View: Is it possible to be timely, compliant *and* meaningful?
***Solange Rohou**, AstraZeneca, United Kingdom & **Antonio Ferrari**, Chiesi Farmaceutici, Italy*

10:05 Q&A

10:15 Keynote Academia View: Title to be determined
***Christoph Schuhmacher**, European Clinical Research Infrastructure Network (ECRIN), France*

10:35 Q&A

10:45 Coffee Break & Posters Viewing

SESSION 2: Current Initiatives

Chairperson: *(invited)*

11:15 The MRCT Center at Harvard - Toolkit and Guidance for Implementation of Returning Results to Study Participants
***Laurie Myers**, Merck, USA*

11:50 The view from the UK Health Research Authority
Speaker invited

12:10 The view from the European Commission
Speaker invited

12:30 Highlights from the posters

12.45 Lunch & Posters Viewing

SESSION 3: How to Communicate Successfully to the Patient Community?

Chairperson: ***Giulio Maria Corbelli**, European AIDS Treatment Group (EATG), Italy*

13:45 EATG Case Study
Speaker invited

14.00 A Sponsor Example
Speaker invited

14.15 How to write a lay summary
Speaker invited

14.30 Panel & Open Forum on How to make lay summaries successful?
Panelists: ***Speakers of the session***
***Jan Geissler**, European Patients' Academy on Therapeutic Innovation (EUPATI), Germany*

Discussion Points: Managing expectations; choosing the right language

15:15 Coffee Break & Posters Viewing

SESSION 4: A Vision for the Lay Summary: Roadmap till 2020

15:30 Panel and Open Forum Discussion

Panelists: ***Angelika Joos**, Merck Sharp & Dohme, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium*

***Laurie Myers**, Merck, USA*

Academia, Patient Organisation and Ethics Committee representatives invited

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

16:40 End of Workshop