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: In Partnership with:

conferences@efgcp.eu - www.efgcp.eu
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 interventional 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
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Kaisa Immonen-Charalambous European Patients’ Forum (EPF), Belgium
Angelika Joos Merck Sharp & Dohme, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
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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
Antonio Ferrari  Chiesi Farmaceutici, Italy
Jan Geissler  European Patients’ Academy on Therapeutic Innovation (EUPATI), Germany
Andrea Heckenberg  Medical University of Vienna, Austria
Amanda Hunn  Health Research Authority (HRA), United Kingdom
Kaisa Immonen-Charalambous  European Patients’ Forum (EPF), Belgium
Robert Johnstone  International Alliance of Patients’ Organisations, United Kingdom
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, Inc.,
Khafil Moudachirou  AIDES, France
Laurie Myers  Co-chair of the Multi-Regional Clinical Trials (MRCT) Center Return of Results initiative, Harvard University, Merck & Co, Inc, USA
Peter O’Donnell  Politico, Belgium
Sir Nick Partridge  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
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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: Robert Johnstone, International Alliance of Patients’ Organisations, United Kingdom

11:15  The MRCT Center at Harvard - Toolkit and Guidance for Implementation of Returning Results to Study Participants
       Laurie Myers, Co-chair of the Multi-Regional Clinical Trials (MRCT) Center Return of Results initiative, Harvard University, Merck & Co, inc, USA

11:50  The EMA / UK Health Research Authority approach a successful lay summary process in Europe
       Amanda Hunn, Health Research Authority (HRA), United Kingdom

12:10  The view from the European Commission
       Speaker invited

12:30  Q&A

12:45  Lunch
SESSION 3: How to Communicate Successfully to the Patient Community?

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

13:45 Case Study - Results dissemination of the IPERGAY study
Khafil Moudachirou, AIDES, France

14.00 A Sponsor Example: PfizerLink: A Patient Community Platform - How Pfizer, Inc. maintains post-clinical trial relationships with participants
David Leventhal, Pfizer, Inc.

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

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

15:30 Panel and Open Forum Discussion
Moderator: Peter O’Donnell, Politico, Belgium
A Vision for the Lay Summary: Roadmap till 2020
Sir Nick Partridge, United Kingdom

Panelists: Angelika Joos, Merck Sharp & Dohme, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
Laurie Myers, Co-chair of the Multi-Regional Clinical Trials (MRCT) Center
Return of Results initiative, Harvard University, Merck & Co, Inc, USA
Andrea Heckenberg, Medical University of Vienna, Austria
Kaisa Immonen-Charalambous, European Patients’ Forum (EPF), Belgium
Robert Johnstone, International Alliance of Patients’ Organisations, United Kingdom

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

16:40 End of Workshop