Final Workshop

Patients Partnering in Clinical Trials

7 & 8 December 2010
Management Centre Europe
Brussels, Belgium
Programme Committee

Melissa Hillier  Genetic Alliance UK, United Kingdom
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Ingrid Klingmann  European Forum for Good Clinical Practice (EFGCP), Belgium
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Faculty

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Jacqueline Bowman  European Platform for Patients’ Organisations, Science & Industry (EPPOSI), Belgium
Valter Dal Pos  European Association Friends of McCune Albright Syndrome (Eamas), Italy
Inez de Beaufort  European Group on Ethics (EGE), The Netherlands
Pim de Boer  Asthma Foundation, The Netherlands
Jacques Demotes  European Clinical Research Infrastructures Network (ECRIN) & INSERM, France
Juan Garcia Burgos  European Medicines Agency (EMA)
Mike Hardman  AstraZeneca, United Kingdom
Candy Heberlein  Foundation for the Advancement of Bone Marrow Transplantation, Switzerland
Melissa Hillier  Genetic Alliance UK & PatientPartner, United Kingdom
Stephanie Hoffmann  Genzyme, Belgium
François Houÿez  EURORDIS, France
Karen Inns  National Cancer Research Network, United Kingdom
Ingrid Klingmann  European Forum for Good Clinical Practice (EFGCP) & PatientPartner, Belgium
Pierre Mallia  Medical School, University of Malta
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Jeremiah Mwangi  International Alliance of Patients' Organizations (IAPO), United Kingdom
Detlef Niese  Novartis Pharma, Switzerland
Cor Oosterwijk  Dutch Genetic Alliance (VSOP), PatientPartner Coordinator, The Netherlands
Sue Pavitt  University of Leeds, United Kingdom
Representative  European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium (invited)
Workshop Language

The language of the Workshop will be English.

Workshop Rationale

With this Final European workshop, PatientPartner marks its last major dialogue session with all of the involved stakeholders on how the patient’s perspective can be imbedded in clinical trials. In the previously held Regional European workshops four of the major questions surrounding this new partnership have been explored:

- What role should patient organisations have in clinical trials?
- What knowledge is needed for patient organisations to fulfil this new role?
- What do the stakeholders need to know about each other to be able to engage in partnership in clinical trials?
- Which action plans are needed to facilitate partnership in clinical trials?

Throughout the regions our workshops showed that patient organisations wanted to be involved in all stages of the clinical trial development process to ensure the patient perspective was incorporated into the resulting trials.

Furthermore important roles were seen for patient organisations in providing information on where to find and how to take part in clinical trials to their members as well as having a say in the agenda setting and ethical review of clinical trials.

For academia and the pharmaceutical industry patient organisations were found to have an important role in making protocols more patient-oriented and patient information and informed consent documents more understandable. Furthermore these two stakeholder groups foresaw a role for patient organisations in facilitating patient recruitment as well as raising awareness on the availability and opportunity to take part in clinical trials in Europe.

On the topic of the need for knowledge all represented stakeholders agreed that for patient organisations to fulfil their “new” role as a partner in clinical trials a certain level of training on the clinical trials development process needed to be provided.
Finally the conjoined stakeholders identified that both patient organisations and Academia and pharmaceutical industry struggle in the identification of the “right” partner to work with on a certain clinical trial as well as lack the knowledge of each other’s competencies and drivers to do so.

The regional workshops ended with two main themes that were worked out in action plans:
- A training program for patient organisations
- A matchmakers database to facilitate the finding of partners in clinical trials

With these questions answered (www.patientpartner-europe.eu/en/workshops) and a number of action themes identified this final workshop will focus on how to make the partnership between patient organisations and other stakeholders in clinical trial development work in practice.

There will be three breakout sessions during the workshop:
- The first breakout session will focus on the “ethical principles” that are needed for patient organisations and the other stakeholders to work together in an ethical manner.
- The second breakout session will focus on how to “build the bridge” to partnership: looking at the practical issues in working together in clinical trial development.
- The third breakout session will focus on how to “build the PatientPartner Communication platform” in order to fulfil the need for a matchmaking structure that was identified in the three regional workshops.

As a backdrop to the workshop there will be an ongoing poster exhibition with a poster session at the end of day one showcasing examples of the active involvement of patient organisations in clinical trials.

The resulting outcomes of the final workshop will be used for the completion of the Patientpartner code of ethics, practical guidelines for all stakeholders how to actively engage with each other in clinical trials as well as preparing recommendations for the European Commission and local authorities. Feedback will be sought continuously through PatientPartner’s newsletter from all stakeholders to validate these products as well as disseminate them to a broader European public.

About PatientPartner
PatientPartner is a European project investigating, enforcing and advising on the role of patient organisations in clinical trials (www.patientpartner-europe.eu). The project’s main goals are:
- to make inventories of:
  o the needs of patient organisations regarding their involvement in clinical research;
  o the needs and expectations of other involved stakeholders;
- to identify and realise common points of action amongst all stakeholders through engaging in an active dialogue;
- to realise a European Network of Patients partnering in Clinical Research (ENPCR) to support the projects’ goals with their advice and to create a European network for interaction with the other stakeholders in the clinical trial field;
- to create European, patient-centred guiding tools and recommendations on how to create a successful partnership in the clinical trials context.
Agenda

Tuesday 7 December 2010

09:45  Registration and Welcome Coffee

10:30  Welcome and Introduction to the PatientPartner Project

**Cor Oosterwijk**, Dutch Genetic Alliance (VSOP), PatientPartner Coordinator, The Netherlands

**Plenary Session 1**

**Introduction**

Chairperson: **Cor Oosterwijk**, Dutch Genetic Alliance (VSOP), PatientPartner Coordinator, The Netherlands

10:40  Keynote Introduction

*Speaker invited*

11:10  The PatientPartner project & the outcomes of the regional workshops

**Kim Wever**, Dutch Genetic Alliance (VSOP) & PatientPartner, The Netherlands

11:40  Active Patient Involvement in Clinical Trials?

**Hazel Thornton**, Independent (lay) Advocate for Quality in Research and Healthcare, United Kingdom

12:00  Lunch

**Break-out Session A**

**Ethical Principles in Partnership**

13:00  Introduction to the Break-out groups Session A

**Inez de Beaufort**, European Group on Ethics (EGE), The Netherlands

13:15  Break-out groups - Session A on ‘Ethical Principles in Partnership’

- **Group A1** – Chair: **Inez de Beaufort**, European Group on Ethics (EGE), The Netherlands
  Rapporteur: **Luc Stuit**, Association Française pour la Recherche sur la Trisomie 21 (AFRT), France

- **Group A2** – Chair: **Ingrid Klingmann**, European Forum for Good Clinical Practice (EFGCP) & PatientPartner, Belgium
  Rapporteur: **Stephanie Hoffmann**, Genzyme, Belgium

- **Group A3** – Chair: **Cees Smit**, Dutch Genetic Alliance (VSOP), The Netherlands
  Rapporteur: **Pierre Mallia**, Medical School, University of Malta

14:45  Coffee Break

15:15  Reports from the 3 Break-out groups – Session A

Chaired by **Cor Oosterwijk**, Dutch Genetic Alliance (VSOP), PatientPartner Coordinator, The Netherlands
Break-out Session B

Building Bridges to Partnerships

16:15  Introduction to the Break-out groups Session B
Detlef Niese, Novartis Pharma, Switzerland

16:30  Break-out groups - Session B on ‘Building Bridges to Partnerships’

Group B1 –  Chair: Detlef Niese, Novartis Pharma, Switzerland
Rapporteur: Candy Heberlein, Foundation for the Advancement of Bone Marrow Transplantation, Switzerland

Group B2 –  Chair: Sue Pavitt, University of Leeds, United Kingdom
Rapporteur: Valter Dal Pos, European Association Friends of Mc Cure Albright Syndrome (Eamas), Italy

Group B3 –  Chair: Rod Mitchell, European Genetic Alliances Network (EGAN) & PatientPartner, United Kingdom
Rapporteur: Leandros Arvanitakis, Pfizer, Greece

18:00  Poster Session & Cocktail party
20:00  End of cocktail

Wednesday 8 December 2010

8:45   Reports from the 3 Break-out groups – Session B
Chaired by Kim Wever, Dutch Genetic Alliance (VSOP) & PatientPartner, The Netherlands

9:45   Introduction to the Break-out groups Session C
Melissa Hillier, Genetic Alliance UK & PatientPartner, United Kingdom

10:00  Coffee Break

Break-out Session C

Building the PatientPartner Communication Platform

10:30  Break-out groups C on ‘Building the PatientPartner Communication and Networking Platform’

Group C1 –  Chair: Melissa Hillier, Genetic Alliance UK & PatientPartner, United Kingdom
Rapporteur: Piotr Sawicki, Medical Centre Osteomed, Poland

Group C2 –  Chair: Pim de Boer, Asthma Foundation, The Netherlands
Rapporteur: Tomasz Szelagowski, Federation of Polish Patients, Poland

Group C3 –  Chair: Mike Hardman, AstraZeneca, United Kingdom
Rapporteur: Karen Inns, National Cancer Research Network, United Kingdom
12:00  Reports from the 3 Break-out groups – Session C
   Chaired by **Kim Wever**, Dutch Genetic Alliance (VSOP) & PatientPartner, The Netherlands

13:00  Lunch

14:00  Panel & Open Discussion on **How to Build on PatientPartner Results**
   Chaired by **Ingrid Klingmann**, European Forum for Good Clinical Practice (EFGCP) & PatientPartner, Belgium
   Panelists:  **Jeremiah Mwangi**, International Alliance of Patients’ Organizations (IAPO), United Kingdom
              **François Houÿez**, EURORDIS, France
              **Liuska Sanna**, European Patients Forum, Belgium
              **Representative**, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium (invited)
              **Juan Garcia Burgos**, European Medicines Agency (EMA)
              **Jacques Demotes**, European Clinical Research Infrastructures Network (ECRIN) & INSERM, France
              **Jacqueline Bowman**, European Platform for Patients’ Organisations, Science & Industry (EPPOSI), Belgium

15:50  Closing Remarks
   **Kim Wever**, Dutch Genetic Alliance (VSOP) & PatientPartner, The Netherlands

16:00  End of Workshop