



Southern European Regional Workshop

**Defining the needs and means for
more partnership between Patients,
Patient Organisations and Other
Stakeholders in Clinical Trials**

**24 and 25 March 2010
Athens, Greece**

Southern European Regional Workshop





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Programme Committee

Corinne Gaillard	European Forum for Good Clinical Practice (EFGCP), Belgium
Melissa Hillier	Genetic Interest Group (GIG), United Kingdom
Alastair Kent	Genetic Interest Group (GIG), United Kingdom
Ingrid Klingmann	European Forum for Good Clinical Practice (EFGCP), Belgium
Rod Mitchell	European Genetic Alliances' Network (EGAN), United Kingdom
Cor Oosterwijk	Dutch Genetic Alliance (VSOP), PatientPartner Coordinator, The Netherlands
Ariadne Stamatopoulou	Genetic Interest Group (GIG), United Kingdom
Kim Wever	Dutch Genetic Alliance (VSOP), PatientPartner Officer, The Netherlands

Faculty

Stephan Dressler	European Aids Treatment Group (EATG), Germany
Melissa Hillier	Genetic Interest Group (GIG), United Kingdom
Ingrid Klingmann	European Forum for Good Clinical Practice (EFGCP), Belgium
Rod Mitchell	European Genetic Alliances' Network (EGAN), United Kingdom
Cor Oosterwijk	Dutch Genetic Alliance (VSOP), PatientPartner Coordinator, The Netherlands
Ariadne Stamatopoulou	Genetic Interest Group (GIG), United Kingdom
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Workshop Language

The language of the Workshop will be English.



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Workshop Rationale

When we think of the role of patients in clinical research, this might be limited to the thought of a patient being a 'subject' in a clinical trial. However, patients and patient organisations have much more to offer the clinical trial process. By using their experiential knowledge, patients have a potential role as partners in clinical research. A partnership between patients, patient organisations and the other key stakeholders – e.g. pharmaceutical companies and clinical researchers – will create new paradigms from which not only the patient will benefit, but also the quality, quantity and effectiveness of clinical research. In the end, such partnerships will contribute to better, patient-centred health care, and hopefully a more cost-effective quality research.

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:
 - the needs of patient organisations regarding their involvement in clinical research;
 - 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.

After the first Central PatientPartner Workshop in Brussels (11 June 2009), three two-day **Regional Workshops** are organised in three European regions:

- The North-Western European Workshop, was held on 12 and 13 October 2009 in London, United Kingdom;
- The Central-Eastern European Workshop will be held on 30 November and 1 December 2009 in Budapest, Hungary;
- The Southern European Workshop will be held on 24 and 25 March 2010 in Athens, Greece.

These three regional workshops are meant for dialogue on regional-specific opportunities and hurdles towards more partnership in clinical trials, for example in relation to access to information, patients' rights, cultural and political aspects, relationship between the various stakeholders, etc. Your input as stakeholders is of a key importance, not only for these workshops but also for the implementation of the project's results in your own region in the near future.

The information gained from the workshops and throughout the project will play an important part in creating recommendations for more and better patient partnership in the clinical trial process. The resulting recommendations will be further discussed and developed during a Final Central Workshop (Brussels, 2010). In the third and final year of the project (2010-2011), the recommendations will be worked out further and then addressed to key European stakeholders such as regulatory bodies, academia, industry, policy-makers, patient organisations, etc. Finally, the end report of the PatientPartner project, including all reports, recommendations and guides, will be presented to the European Commission who may then use the outcomes to prepare future policy on clinical trials.



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The **North-Western European Workshop**, the first of the three (12 and 13 October 2009), will bring together stakeholders knowledgeable about the situation in Austria, Belgium, Denmark, Finland, Germany, Ireland, Luxembourg, Sweden, The Netherlands, the United Kingdom and also Iceland, Liechtenstein, Norway and Switzerland.

The **Central-Eastern European Workshop**, the second of the three (30 November and 1 December 2009), will bring together stakeholders knowledgeable about the situation in Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia and also Albania, Belarus, Bosnia Herzegovina, Croatia, Macedonia, Moldova, Montenegro, Serbia, Ukraine.

The **Southern European Workshop**, the last of the three (24 and 25 March 2010), will bring together stakeholders knowledgeable about the situation in Cyprus, France, Greece, Italy, Malta, Portugal, Spain and also Andorra, Gibraltar, Monaco, San Marino, Turkey, Vatican.

There will be a number of break-out and plenary sessions throughout the workshops. In each workshop, the focus will be on generating ideas to move towards partnerships between all stakeholders, in the first place in the region in which the workshop has been set and secondly throughout Europe.

- The first break-out session will focus on the role Patient Organisations want to play and the areas in which Industry and Investigators find Patient Organisation participation desirable.
- In the plenary session thereafter, the outcomes of the first break-out session will be debated on.
- The second break-out session will focus on what knowledge stakeholders would need in order for Patient Organisations and other clinical trial stakeholders to become partners.
- In the following plenary session, stakeholders will have the chance to work together to define actions that have to be taken in order to achieve the ideal world of day 1.
- In the final session of the day, the proposed actions will be prioritised and a joint multi-stakeholder action-list will be defined as means to move forward to the Final Workshop.

This 3-year project is funded by the EU Seventh Framework Programme (FP7) and operated by a consortium consisting of the Dutch Genetic Alliance (VSOP, project coordinator), the European Forum for Good Clinical Practice (EFGCP), the European Genetic Alliances' Network (EGAN) and the Genetic Interest Group (GIG).

Region Definitions

Central-Eastern Europe

Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia
+ *Albania, Belarus, Bosnia Herzegovina, Croatia, Macedonia, Moldova, Montenegro, Serbia, Ukraine*

Southern Europe

Cyprus, France, Greece, Italy, Malta, Portugal, Spain
+ *Andorra, Gibraltar, Monaco, San Marino, Turkey, Vatican*

North-Western Europe

Austria, Belgium, Denmark, Finland, Germany, Ireland, Luxembourg, Sweden, The Netherlands, United Kingdom
+ *Iceland, Liechtenstein, Norway, Switzerland*



Agenda

24 March 2010

- 10:15 Registration and Welcome Coffee
10:45 Opening and Welcome
Cor Oosterwijk, VSOP, PatientPartner Coordinator, The Netherlands

Clinical Trials and Patients Today

Plenary Session 1

Chairperson: Cor Oosterwijk, VSOP, PatientPartner Coordinator, The Netherlands

- 10: 50 Why is Partnering in Clinical Trials Important?
Ingrid Klingmann, EFGCP, Belgium
- 11:25 PatientPartner Project: Presentation and Regional Survey Results
Kim Wever, VSOP, PatientPartner Officer, The Netherlands
- 12:00 Charters of Patients' Rights
Ariadne Stamatopoulou, GIG, United Kingdom
- 12:20 How do Patient Organisations and Patients Find Out About Clinical Trials?
Stephan Dressler, EATG, Germany
- 12:40 Discussion: Why is it Difficult for Patients to Participate in Clinical Research? – Share Your Experience
- 13:00 Lunch

Working Together Towards an Ideal World in Southern Europe

Break-out Session A

- 14:00 **Working Groups 1 and 2: What Role do Patient Organisations Want to Play?**
Facilitators: Ariadne Stamatopoulou, GIG, United Kingdom
Kim Wever, VSOP, PatientPartner Officer, The Netherlands
- Working Group 3: What Role do Investigators Want Patient Organisations to Play?**
Facilitator: Rod Mitchell, EGAN, United Kingdom
- Working Group 4: What Role do Pharmaceutical Industry Researchers Want Patient Organisations to Play?**
Facilitator: Ingrid Klingmann, EFGCP, Belgium
- 16:00 Coffee Break



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What Does the Ideal World Look Like in Southern Europe?

Plenary Session 2

Chairperson: Cor Oosterwijk, VSOP, PatientPartner Coordinator, The Netherlands

16:20 Plenary Debate on the Working Groups Outcomes
Facilitators of the Break-out Session A

17:40 Summary
Ingrid Klingmann, EFGCP, Belgium

18:00 End of Day 1

25 March 2010

**What do the Stakeholders Need to Know to Fulfil their Roles in the Southern
European Multi-Stakeholder Ideal World?**

Break-out Session B

08:30 **Working Groups 1 and 2:** Patient Organisation Representatives: What do Patient Organisations Need to Know about Clinical Trials? What do Patient Organisations Need to Know about their Partners?
Facilitators: Ariadne Stamatopoulou, GIG, United Kingdom
Kim Wever, VSOP, PatientPartner Officer, The Netherlands

Working Group 3: Clinical Researchers and Members of Academia: What do Patient Organisations Need to Know about Clinical Trials, according to Investigators? What do Investigators Need to Know about Patient Organisations?
Facilitator: Melissa Hillier, GIG, United Kingdom

Working Group 4: Pharmaceutical Industry Researchers: What do Patient Organisations Need to Know about Clinical Trials, according to Pharmaceutical Industry Researchers? What do Pharmaceutical Industry Investigators Need to Know about Patient Organisations?
Facilitator: Ingrid Klingmann, EFGCP, Belgium

10:30 Coffee Break



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Actions Towards Achieving the Ideal World

Plenary Session 3

Chairperson: Cor Oosterwijk, VSOP, PatientPartner Coordinator, The Netherlands

- 10:50 Reports from the Break-out Session B
Facilitators of the Break-out Session B
- 11:20 Multi-Stakeholder Table Discussions: Actions to Overcome the Hurdles
Facilitators from the PatientPartner Project Team
- 13:00 Lunch

What Needs to be Done to Achieve the Ideal World?

Plenary Session 4

Chairpersons: Ingrid Klingmann, EFGCP, Belgium
Kim Wever, VSOP, PatientPartner Officer, The Netherlands

- 14:00 Report from the Multi-Stakeholder Discussions
Facilitators from the Multi-Stakeholder Table Discussions
- 14:50 Prioritisation of the Action Points
- 15:00 Coffee Break
- 15:20 Plenary Discussion: Summary and Action Plan in Sight of the Final PatientPartner Workshop
- 16:20 Summary and Closure
- 16:30 End of the Workshop