



BRINGING PATIENTS INTO RESEARCH

Report of the PatientPartner Southern Europe Regional Workshop on Patients Partnering in Clinical Research, held at the Divani Palace Acropolis Hotel, Athens, Greece, 24 and 25 March 2010

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1: The report and its aim

This report covers the main discussion threads and conclusions from PatientPartner's Southern Europe Regional Workshop on Patients Partnering in Clinical Research, held in Athens on 24 and 25 March 2010 and attended by delegates from 7 countries in the region: Cyprus, France, Greece, Italy, Malta, Portugal, Spain and Turkey.

This was the third in a series of regional workshops following the launch of the PatientPartner project in Brussels in July. Its results will feed in to the final workshop, to be held in the autumn of



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2010, alongside those of the North-Western Europe (held on 12 and 13 October 2009) and Central-Eastern regions (held on 30 November and 1 December 2009).

The report has been produced by the workshop rapporteur, Peter Wrobel, who takes full responsibility for its content.

2: Introduction: PatientPartner

PatientPartner is a €950,000 project led by the Dutch Genetic Alliance (VSOP), the European Forum for Good Clinical Practice (EFGCP), the European Genetic Alliances' Network (EGAN) and the Genetic Interest Group (GIG). It is funded by the European Commission as part of the 7th Framework Programme.

The three-year project began in May 2008. It aims to identify patient needs for partnership in the clinical trial context, develop dialogue with other stakeholders on those needs and identify regional differences, and come up with strategies and possibly binding recommendations on how to work with patient organisations in clinical research. It covers all diseases and all areas of biomedical and pharmaceutical research.

3: Executive summary and key messages

As with the two earlier regional workshops, the bulk of the time was spent working in small groups on particular questions and problems, rather than listening to formal presentations.

The PatientPartner project opted for regional workshops because it suspected that the challenges faced in bringing together patients and clinical research might vary regionally. This was the third and final regional workshop, and the discussions followed the same thread as the two previous workshops. Before any final conclusions are drawn about a uniform approach in Europe, however, the project awaits the final PatientPartner meeting in Brussels in October 2010, which will comprise delegates from all regions in Europe.

The Athens meeting came up with four clear core proposals:

- To work for a database for all stakeholders in clinical trials, with the principal aim of enabling stakeholders to find the right partners.
- To write to the European Commission to encourage a renewed emphasis on patient partnership, in particular urging it to support the database, training and education, moves to widen early access to treatments, the development of a code of conduct for partnership in clinical trials, and the development of guidelines on privacy and confidentiality for all stakeholders.
- To encourage the formation of umbrella patient organisations nationally and regionally, both at the level of individual indications and more generally.



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- To enhance communication among patient organisations through workshops, a newsletter and the European Network for Patients Partnering in Clinical Research (EN-PCR).

4: Workshop structure

The core proposals were the result of the final session of the workshop, which itself followed from sessions where the participants, meeting separately and together, came up with the key steps that they thought would most advance the idea of patients as partners in clinical research.

The workshop began with presentations about why partnering in clinical trials is important, PatientPartner's survey of involvement across Europe, charters of patients' rights, and how patients can find out what researchers are doing and what trials they might be a part of.

A plenary session then looked at why it can be so difficult for patients and patient organisations to participate in clinical trials, based on the experience of the workshop delegates.

Breakout groups of delegates from patient organisations, academia and industry then considered what the ideal world of patient participation in Southern Europe might look like, coming up with a series of recommendations. The recommendations were discussed in a plenary session, with discussion ending with consensus agreement on three proposals (that does not mean lack of agreement on the others: time was limited).

The next day, the workshop divided again into breakout groups of patient organisations, industry representatives and academic and clinical researchers to lay the basis for prioritisation by setting out what the stakeholders would need to know about each other in order to form successful partnerships. Then delegates organised in multi-stakeholder round tables to prepare recommendations for action plans to deal with the main challenges perceived.

Those proposed solutions were subjected to discussion in the final plenary session, which agreed the key steps set out briefly in the Executive Summary (and in more detail in section 10).

5: Clinical trials and patients today

Why is partnering in clinical trials important?

Ingrid Klingmann, from the European Forum for Good Clinical Practice, Belgium, gave an overview of the history and development of clinical trials. In doing so, she had a double aim: to establish a common level of understanding, and to give an idea of why her own personal commitment to partnering in clinical trials.

She followed the history of drug development through from centuries where plants formed the only basis for formulations through to the birth of synthetic drugs in the 1930s and 1940s. Molecular targets began to play a part only in the 1950s – which also saw the beginning of regulation for safety, as a result of the thalidomide tragedy.



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After summarising the current phases of drug development, the questions that researchers seek to answer in the process and how studies are designed, Ingrid Klingmann turned to the situation now: exploding costs, fewer drugs in development – and even fewer drugs coming onto the market. Every company would like to find “blockbuster” drugs, but the low-hanging fruit, the easy drugs, have all been found and brought to market – hence the current moves in the direction of personalised medicine.

If new drugs are to be developed, we have to have new concepts, and “new concepts often means new partners”. The large companies used to do everything themselves; now they work more and more with small biotech companies, as well contract out other activities, such as organising trials, to clinical research organisations.

“We are now at the beginning of a new phase in this collaborative development,” she said, “collaboration with patients. The patient organisations are now seen as a very important potential partner to improve the situation.”

The advantages are clear: faster and more reliable access to patients; more understandable patient information sheets, so patients will be more likely to take part in trials; protocols better adapted to the needs of patients; better feedback from patients; and, “last but not least” the involvement of patients in the overall process could substantially improve the image of trials.

Patient organisations are better able to serve their members through greater understanding of the drug development process, more information on the availability of clinical trials (thereby increasing access to treatment for many patients), and better-informed lobbying on key issues of concern. Researchers win, too, through better and faster recruitment of patients to clinical trials (and retention during the trials) and through better-quality data.

So all the partners – patients, industry, academia gain: the indications addressed become more relevant to patients; drug development will become cheaper and quicker; data become more reliable; confidence in the new treatments rises; and access to treatment becomes more transparent and more fair. “Only if we establish this three-way collaboration can we approach the challenges of individualised medicine,” she concluded.

Jane Pittadaki from the Greek Haemophilia Society wanted to know how, exactly, patient participation would make access more transparent and fair. That’s because the process whereby a drug is selected to be developed tends to be kept completely within the pharmaceutical company, said Ingrid Klingmann, with decisions being taken on the basis of the company’s commercial priorities. “But patients have other priorities,” she said, and a better collaboration with patients might make it possible for patients – in some degree – to influence companies’ decisions and to feed back to patients what they have achieved and the compromises that have been made.



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The PatientPartner Survey

PatientPartner is now in its second year, and Project Officer Kim Wever gave delegates an overview of progress so far. These include a literature search, an investigation of best practices and the setting up of the European Network of Patients Partnering in Clinical Research, EN-PCR.

The EN-PCR is a virtual network with a focus on paediatrics, registries and biobanks, ethics, information and education – “plus what you come up with today”, she said. The problems are much the same across Europe. “Whether in Helsinki or Madrid, people on the street do not know what a clinical trial is. So we need those who do know to get involved.”

There are many reasons for lack of involvement, including being unaware of the benefits, and an absence of legislation requiring patient involvement. There is also uncertainty about whom to contact, whether in industry, academia or in the patient organisations – with at least 38,000 patient organisations in Europe, finding the right one is a challenge.

In order to find out just what the involvement currently is, PatientPartner surveyed patient organisations on how they are involved, using six possible levels of involvement: as driving force, co-researcher, reviewer, advisor, information provider, and as research subject. The survey comprised responses from 205 patient organisations across 13 countries, 12,000 emails, a literature search, and a number of structured interviews. A general summary of the survey is contained in the report of the Start-Up Workshop in Brussels in June 2009, and can be read at www.patient-partner.eu.

Contrary to expectations, the survey revealed only small differences overall between patient involvement in the different regions. Southern European countries are somewhat more involved in helping to find funding for clinical trials, especially for rare diseases, and very active in translating the information that is out there into patient-friendly language. And more patients appear to take part in trials as research subjects than in other regions of Europe.

Patient organisations in the region are also very involved in biobanking activities. But – as in other regions of Europe – they tend to have a low level of involvement in research into children’s medicines. Wever ascribed the lack of involvement in paediatrics to the fact that clinical trials in children are relatively new. “Hopefully when we do this research in ten years there will be more involvement,” she said.

Charters of Patients’ Rights

Ariadne Stamatopoulou from the Genetic Interest Group, UK, presented Internet-based research she had conducted on the legal rights that patients have in treatment and in clinical trials in different countries across Europe, and across the region in particular.

Most of the rights relate to areas outlined in the Declaration of Helsinki, adopted in 1964 and amended eight times since. It deals with four main areas: informed consent, the right to information on one’s own health, the right to one’s own medical file; and rights to complain and to compensation.



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She explained that although the Declaration is not legally binding, it is often used as a guideline for charters of patients' rights. When it comes to having such charters, or not, there are no significant differences between the different regions of Europe. Charters have been signed and ratified in Cyprus, Greece, Portugal and Spain, while France and Italy are awaiting ratification of their signed charters.

Most countries in Southern Europe have at least some information on rights for children – but there are “a lot of gaps”, she said. For example, she was unable to find any information from any country in the region about a minor's right for information on the current state of their health. However, Cyprus and France give children the right to access their medical file, usually with the supervision of an adult.

A recent survey on the participation of under-16s in clinical trials as healthy volunteers in 17 countries has shown that, in the region, only France allows this, while Cyprus, Greece and Italy do not.

Finding out what's going on

Few patient organisations have as much experience in partnering in clinical trials – at all levels – as the European AIDS Treatment Group, and Stephan Dressler from the EATG was at hand to give delegates the benefit of his experience.

The EATG has its origins in Western and Central Europe, but has expanded to the south and east, a process that made him realise that the questions that patient organisations have in each region are “quite different”. So much so, in fact, that when people from countries such as Spain, Greece, Italy and Portugal joined the EATG they formed a Southern States Working Group to address their particular needs, especially in regards to access to treatments.

What patients wish to find out about clinical trials will vary, he said. “It may differ from country to country, from region to region and from disease to disease. It will be different if there is no treatment at all. You may also be giving social support to patients, especially in chronic diseases, and it may be different with old or young patients.”

Stephan Dressler discussed four aspects: participation in clinical trials, involvement in trial design, upcoming clinical trials, and trial results.

Information about clinical trials is available through multiple channels, including physicians, care providers, and national and European patient networks. Internet resources include www.clinicaltrials.gov, run by the US National Library of Medicine, which holds information on more than 80,000 clinical trials, including some outside the US. This year a European equivalent, EudraCT, should be online and freely available, though one limitation could be that it will only list trials going through the European Medicines Agency's centralised procedure – for small regional or local trials it might be best to check with individual countries' health or consumer protection ministries.

He also pointed to clinical trials matching services, which are popular in the US and might well become more used in Europe, and company websites as sources of information.



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Patient organisations that wish to be involved in the design of clinical trials have multiple opportunities for getting their views across. These might be, for example, about inclusion and exclusion criteria, or about particular combinations of treatment to be considered. A simple way to open dialogue is to approach the investigators or company concerned. Regulatory authorities may also be helpful, particularly for rare diseases where there is no treatment – pharmaceutical companies looking to develop a treatment will often consult with the regulators about how to proceed.

What's in the pipeline? That's always useful information, he said. Information about upcoming trials can be obtained from the scientific literature and from conferences, but also from pharmaceutical companies themselves. You don't have to check the whole literature and every conference: screening services such as the US Pubmed (www.ncbi.nlm.nih.gov/pubmed) that you can get to search for you. And again, investigators and academic researchers are useful contact partners.

The results of trials are normally released first at scientific conferences, so it is important to identify the ones in your area. But conferences can be costly to travel to and attend, so Stephan Dressler recommended that patient organisations build this into their budgets. Yes, he said, one can listen to conference webcasts, but it's not the same as being there and listening to the discussion in the corridors. Trial results are also published, with a delay of course, in scientific journals and on company websites (beware, though, of potential bias in the presentation of results, he said), and by some regulators.

Always identify the information provider, he concluded: know who gives you the information – it may be linked to a hidden agenda – and try to double-check with other sources. He urged patient organisations providing information to patients to tell them where the information comes from as well as who you are.

But what patient organisations want and how they want to do it is up to them. "There are lots of people telling patient organisations what they should do," he said. "Patient organisations should set their own agenda in each country and in each disease area. I'm not going to tell you what to do. Patient organisations should define their own priorities, not companies or politicians."

6: Plenary Session 1. Why is it difficult for patients to participate in clinical research?

Some patients find it harder than others to take part in clinical research – women in particular. Despite evidence that it would be advantageous in some circumstances to develop different drugs for men and women, women are often ignored, said Matteo Schwarz from NPS Italia Onlus, the Italian network of people living with HIV/AIDS. And some drugs have been withdrawn from the market because of side effects in men even though they have proved to be effective in women. It's an ethical issue that needs to be addressed in the design of trial protocols, he said.

There are reasons for this, said Ingrid Klingmann: the ideal people to study to have the best chance of understanding a drug's effect are healthy young men, who have fewer variations in metabolism than other sections of the population; and there are issues about the effect of drugs on the fetus and on a woman's hormonal balance. "We really do need to go much earlier into drug



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development for women,” she said. “But essentially this is a genetic thing – we need to know not just about male or female but genetic conditions generally. Looked at like this, the decision to include women in trials is only one step towards involving all types of people.”

Patients need to get involved early, in the preclinical phase, said Valter Dal Pos from the EAMAS, the European Association Friends of McCune-Albright Syndrome. “Our job in this workshop should be to establish rules and ways of promoting clinical trials according to criteria determined by patient organisations.” Indeed, said Cor Oosterwijk, who is in charge of the PatientPartner project: getting involved early is one answer to many of the problems.

For Pierre Mallia from the University of Malta Medical School patients are overly dependent on their physicians, and patient organisations need to step in to redress the balance by becoming involved in the recruitment process for clinical trials. This is also something for which they might be paid: information about a trial would be given to potential participants by a patient organisation directly in the disease; in turn these organisations could be receiving badly needed funds and acting as a contact point for patients involved in the research. This would have the added benefit of avoiding the conflict of interest whereby the person obtaining the informed consent is the one doing the research. “Perhaps down the road one could contemplate legislation on this to improve the recruitment process,” he suggested.

Kim Wever pointed out that when PatientPartner asked patient organisations whether they saw a role for themselves in recruitment some were unsure. “It’s always a difficult question,” she said. “The media tends to jump on clinical trials that go wrong.” Some patient organisations she had spoken to would be willing to help out with recruitment in return not for funds, but for partnership and influence on protocols. She also mentioned problems in remaining neutral and unbiased while helping with recruitment.

Ingrid Klingmann felt it was time for a change. “Without a vision we won’t go anywhere,” she said, adding that Pierre Mallia’s suggestion would require a changes in European and national laws – but there are already moves to change European trials legislation. Certainly, some patient organisations will not want to get involved in recruitment, but the others would require training, and a mechanism to ensure that full information flows from the pharmaceutical company to the patient organisations to enable them to communicate effectively with patients.

In her presentation, Kim Wever had cited one patient organisation surveyed as saying that the ideal partnership is based on equal contribution and equal commitment. But Chrysis Michaelides from the European Social Forum of Cyprus wondered how the contribution can be equal. Equality probably needs to be explained in terms of mutual respect for what the parties bring to the table, said Wever: “So if you have a patient organisation representative, an investigator and a pharma representative, it shouldn’t matter who makes the comment, they should be treated in an equal way, regardless of, say, academic training.”

She stressed that patient organisations need to think about the commitment involved: it takes a lot of effort to learn how to work with an ethics committee, for example. On the other side, professionals need to have a commitment to respecting volunteers who might become ill and unable to respond within desired timelines.



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Silvano Berioli, a clinical consultant from Italy, called for trust on all sides. It is also important, he said, to clarify who does what. He said that patient organisations are currently the “weak link in the chain”, and need information in order to function as partners: “In Italy we have something like 18,000 patient organisations, most of them not paid, so if you want to help them we should give them the opportunity to learn.”

For Franco Cavalot from the University Hospital San Luigi Gonzaga, Italy, one task has to be to manage the expectations of patient organisations. Those expectations are high, he said, but science doesn’t move that quickly. There is also the problem that many trials are organised by pharmaceutical companies based in the US or Japan, with the decisions being taken abroad: “I don’t know how you can get involved in the process of initiating those trials.”

And from Luc Stuit from Association Française pour la Recherche sur la Trisomie 21 (AFRT), France, another difficult problem: how to create partnership when there is no partner. “There is no public interest in Down’s syndrome,” he said, and no company developing it. But don’t despair, said Stephan Dressler – no pharmaceutical company or university was looking into AIDS until 1984, even though the first cases were described in 1981.

7: Plenary Session 2: What does the ideal world look like in Southern Europe? Reports from the first round of breakout groups

This session, moderated by Alastair Kent from the Genetic Interest Group, UK, took the form of discussion and voting on some of the 10 propositions that had emerged from breakout sessions during the earlier part of the afternoon.

The propositions were:

- 1. In an ideal world, patient organisations are the contact between patients and all other stakeholders.*
- 2. In an ideal world, patient organisations are advisers to industry on: design aspects; end points; complexity of protocol; informed consent and communication to patients; trials awareness; recruitment of sites and patients; timelines; understandable terminology.*
- 3. In an ideal world, patient organisations have to be involved as a representative on all boards and committees in all stages of a clinical trial with equal power to decide.*
- 4. In an ideal world, patient organisations should be advisors to ethics committees on an on-call basis and on improvement of ethical review process.*
- 5. In an ideal world, patient organisations and academics should control the R&D process in an equal manner.*
- 6. In an ideal world, patient organisations should be partners of industry in stimulating the public debate on: clinical trials/research; identification of indications that need treatment; drugs to be developed; payer interests; improving the image of clinical trials.*



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7. In an ideal world, patient organisations should receive resources from industry that really reflect the contribution they make.

8. In an ideal world, patient organisations force transparency from all stakeholders.

9. In an ideal world, patient organisations participate in the research policy decision-making so that clinical trials match the patients' needs.

10. In an ideal world, patient organisations have to demonstrate competence to be part of the R&D process (organised, resourced, trained).

The first part of the discussion centred on the question of whether these propositions represented some distant goal or were practical aspirations that could be worked for and implemented now – in other words, whether they were in fact part of the real world. As Chrysis Michaelides put it, “These are not for an ideal world. They are things that have to be on the table and be discussed. For us as patients they are very realistic.”

Yes, agreed Rod Mitchell from the European Genetic Alliances' Network, UK. “Most of the stakeholders are waking up to the idea that we have to work together and that we can speak to another.” And in the first vote of the afternoon, a clear majority agreed.

A question of competence

The discussion then moved to competence – or more precisely whether patient organisations should have to demonstrate competence to be involved in the research process. The idea was clearly controversial. “It is for patient organisations to decide that,” said Melissa Hillier from the Genetic Interest Group, UK. “People talk about competence from patient organisations, but they never outline what they mean,” said Stephan Dressler. “I would like to see a good discussion of what competence is, or we drop the idea of requiring it.”

But he added that there were important discussions to be held over the commitment and interest that patient organisations have. “Are the organisations sustainable? Will they be there over a period of time?” he asked. Ingrid Klingmann said that some ethics committees lack the competence to match their powers, and warned that giving patient organisations the same role might substantially delay the process of getting trials going.

Ian Ellul from the Ministry of Health, Malta, pointed out that we already know that patient organisations can contribute much to research, especially in recruitment and in providing information to patients. Luc Stuit's view was that the competencies of patient organisations were not the same as those of other stakeholders in the research process, a view that chimed with many present. And when Alastair Kent took a second vote, this time on the idea that patient organisations have competences of equal value to those of others, but different ones and they should be treated differently, all bar two delegates agreed.

As so often happens, it was the area of disagreement that took the discussion forward. Ariadne Hager-Theodorides from Greece's National Bioethics Commission was one of those voting against,



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and she explained why. "I don't think patient organisations have intrinsic competences," she said. "They have to prove them, the same way the experts have to prove them. With the rest I agree."

Alastair Kent then put a third proposal to the vote: that patient organisations should have to demonstrate their competence in some way. Again, all bar two agreed. One of those who didn't, Anne Micallef from Breast Care Support Group Europa Donna, Malta, wanted to know the criteria. "Who is competent to decide whether I am competent to represent patients in our organisation? Who?" she asked. That's a complex question, said Ingrid Klingmann. "We would have to define the different tasks and then find the competences that in general someone would have. Then you do it on the basis of a self-assessment and an element of trust."

But everyone has something, said Luc Stuit. "With the little competence we have we can say what we need as patient organisations." We know what patients need and can represent that to industry and government, he said.

Alastair Kent summed up the consensus: **"There is general acceptance that patient organisations have competences that they bring that are different but are of value, but they need to be able to show what those competences are."**

A place at the policy table?

Alastair Kent now turned to the proposition that in an ideal world patient organisations should participate in the making of research policy, so that clinical trials match patients' needs. And here differences initially emerged between industry and the patient groups.

"Would I or industry as a whole agree with this?" wondered Annemarie Dillon from Genzyme, the Netherlands. She preferred a case-by-case approach "to ensure that in the clinical trials process the patient perspective is taken on board within the feasibility of the study process".

Making it clear that he was not speaking for the whole industry, Leandros Arvanitakis from Pfizer, Greece, said that every patient organisation is pushing its own agenda. "It will never come down to one patient group pushing a company to do something," he said.

A fair point, suggested Alastair Kent. How does one create a framework where you can hear all the patient voices? That's the real point, said Chrysis Michaelides. "Who is going to prioritise? If companies do it their main target is to maximise profits." But he conceded that each patient organisation starts from its own priorities. His solution: "I believe all the patient groups should organise and propose a list of priorities." These may not be the same as industry's, but they would form a starting point for discussion. "You [industry] have to consider us as one voice. If you consider us separately you have won."

Alastair Kent then brought the discussion to a conclusion: **"Do we agree that patient organisations should participate in the making of research policy decisions?"** he asked; to which Luc Stuit added the caveat that "patients are at the centre of the clinical trial". The vote showed that delegates unanimously in favour.



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A matter of resources

Patient organisations need more funding if they are to play a full part in clinical trials, said Ian Ellul. But where from? The first and obvious place to look is the pharmaceutical industry. "Pharma should be expected to give something in return," said Pierre Mallia. His fellow countryman Josef Busuttill, from the Malta Association of Crohn's and Colitis, agreed: "Every organisation should satisfy the needs of its customers, and in a way we [patient organisations] are customers of the pharma companies, and yes, why not some small percentage of the profits to the patient organisations."

Not everyone agreed. Ionna Graikou from the Pan-Hellenic Association of Women with Breast Cancer, Alma Zois, thought that a levy on pharma companies would make patient organisations part of the industry: "It will be absolutely impossible to maintain our impartiality and independence." She also wondered what other pharma companies might think of a patient organisation receiving funding from a rival. One way round this, suggested Pierre Mallia, would be for industry to put something back by funding research into rare diseases rather than funding patient organisations.

But the majority supported the idea of funding patient organisations through some kind of levy on industry. "Of course we don't sell our independence," said Chrysis Michaelides, "but at the same time we want to be powerful. If you are poor you are nothing."

Everyone else in the clinical trials process, such as clinical research organisations, lawyers, investigators, is paid by pharma companies, said Stephan Dressler. Why not patient organisations? Yes indeed, said Alastair Kent: "Why are patients the only group who do it for nothing?" And patient organisations would not need much, said Luc Stuit – pharma can afford it.

In a vote, all but two of the delegates agreed with an industry levy. One of those against felt that the responsibility should lie with the state, but the majority thought otherwise. However, that still left open the question of how the money would reach the patient organisations. Should it be paid to an independent foundation, asked Alastair Kent, and distributed to the patient organisations according to a formula to be worked out?

That approach won the support of Pfizer's Leandros Arvanitakis. "Direct funding from pharma would be a stronger relationship than anyone would want to have," he said, preferring an intermediary arrangement via a government or independent agency.

Pierre Mallia's earlier suggestion of using the money to fund research rather than patient organisations was echoed by Valter Dal Pos, who argued for "some compensation" for the efforts of families, perhaps by promoting orphan drugs.

The consensus, as formulated by Alastair Kent, was that there should be **"serious consideration to some sort of levy, vested in a trustworthy third party not part of government, that can look at using those resources to target currently unmet medical needs and possibly compensating**



families for the personal cost of participating in medical research". Put to the vote, the proposal was agreed to by all except one delegate.

Convincing the public

Attention now turned to the sixth proposition – which came from the industry stakeholders' breakout group – that patient organisations should be partners of industry in stimulating public debate about clinical trials. "The key word is partners," said Alastair Kent. "Do we think we should get into bed with industry in promoting this together, or would we do better addressing these issues from our own perspectives?"

The discussion, though limited in time, touched on several aspects of the questions. Kim Wever said that when she had surveyed patient organisations, most felt it was a task for government, education and the media rather than for them; before patient organisations start a public debate, they need first to raise awareness of clinical trials among their own members. Anne Micallef wondered where she would find the time to do this. Cor Oosterwijk said that patient organisations need "at least one additional partner" to avoid accusations of bias. And Rod Mitchell suggested that patient networks such as the European Patients Forum and the EN-PCR could take on the task.

Others thought that the concentration of patient organisations and industry – one "dualistic relationship", said Luc Stuit – was unhelpful. And when it came to the vote on the proposition, there were a few against.

Finally, a consensus was found. Re-formulated by Alastair Kent as "**There should be a multi-stakeholder collaboration to support the development of the public understanding of clinical trials**", the proposition was agreed to by all.

8: What do the stakeholders need to know to fulfil their roles in the Southern European multi-stakeholder world: reports from the second round of breakout groups

Day two began with four parallel breakout sessions: one each comprising delegates from academia and industry; and two with representatives from patient organisations. Their discussions centred around information – what they needed to fulfil their roles, and what they needed others to know. As Cor Oosterwijk said, some of the discussion was structural, some less so, but all of it useful. After the breakouts, delegates came together in a plenary session to hear the prioritised outcomes from each group.

The view from academic investigators:

What do patient organisations need to know about clinical trials?

1. The overall process of drug development, including specifics such as where the clinical trial is based, where the contact points are, what the trial is, and who is eligible for the trial.



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2. The extent to which they can be involved in and affect recruitment. This includes issues of liability, of training, and of a code of conduct “so if we all work from the same rule book we know what we are all doing”, as rapporteur Rod Mitchell put it.
3. They need to have sufficient knowledge about the trial, but they don’t want to be overwhelmed. This comes down to training, he said, reporting that overwhelmingly the group supported the idea that information and training should not come from government. Why? Because they felt that if government were tasked with providing it, nothing would ever happen.

What do academic investigators need to know about patient organisations?

1. What the patient organisations do and the areas and patients they cover, including where they are based and the extent of their outreach with the community and other stakeholders.
2. What the objectives of the patient organisations are, and whether they have policies on transparency (including about where the money comes from).
3. The level of patient organisations’ commitment and motivation to work in partnership. Do they really want to work with industry in speeding up and improving the clinical process, for example over recruitment? Some see their objective as giving advice on the disease and are not necessarily interested in clinical trials.

Although not a priority, the investigators also discussed ethics committees. There should be a rule about the number of them, reported Rod Mitchell: there are “thousands, and they are very fragmented”, such that there might not be enough patient representatives to have one on each. “Even other stakeholders on ethics committees are very stretched,” he said.

The view from industry researchers:

What do patient organisations need to know about clinical trials? (Answers prioritised in order.)

1. A “solid and comprehensive” understanding of the overall process of drug development, both in general and specifically in relation to the indication or indications that they cover. This, said rapporteur Ingrid Klingmann, is a basic requirement if patient organisations are to have “a voice at the table”. This includes knowledge about regulatory and ethical frameworks, insurance conditions and the overall legal framework. The group accorded this point the highest priority, since “all stakeholders need to share the same understanding of terminology”.
2. A “good understanding” on the part of patient organisation representatives of the risks and benefits in clinical trials, not just for patients but also for industry and for the drug discovery process, including in specific indications.
3. “Good knowledge” about the process of informed consent. (“We had a long discussion on this, and agreed we were not doing it well.”)



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Other topics that did not make it into the top three priorities: knowing about the importance of timelines in drug development, allied to a fear that patients with physically reduced capability and availability may have problems adhering to timelines that are critical to industry; knowledge about the roles of other stakeholders.

What do investigators need to know about patient organisations?

1. Most importantly, how representative patient organisations are: whom they represent; their geographical scope; their authority within their community; how they fit in with other groups.
2. A double priority: how credible the patient organisation is, and its will to become a true partner. In terms of credibility, its capacity, independence, background and overall knowledge. In terms of will to become a partner, the extent to which it is willing and able to contribute and participate, and its commitment to the common task (including its commitment to the public, for example by the media); that's also a question of "transparency of willingness".
3. The patient organisation's financial position (is it independent?) and its financial expectations.
4. The patient organisation's knowledge gaps, so that industry can help to fill those gaps and help the organisation to reach the expected and required level of partnership.
5. "Last but not least", what a patient organisation's agenda is: what do they want, are they really interested in active involvement in clinical trials or more interested in supporting patients. And, of course, industry would really like to know more about the practical consequences of the disease for the members of the patient organisation.

Antonio Pires from Europa Uomo, a Portuguese group for patients with prostate cancer, wanted to know who would judge the credibility of an organisation, and what the relevance of financial information is.

"We didn't discuss a formal way of assessing credibility," said Ingrid Klingmann. One aspect is having sufficient experience in disease area and of clinical trials in that area in order to be "really helpful", she said, along with the time, energy, resources and people to make collaboration work. With at least 38,000 patient organisations in Europe, it's difficult to decide which to go with in, say, breast cancer (to which Cor Oosterwijk added that patient organisations can find it hard to locate the right company). There is also competition between some patient organisations. One point that can be important is whether a particular patient organisation is willing and able to create a network of national patient organisations to avoid a company having to set up multiple links itself.

Pfizer's Leandros Arvanitakis stressed that industry is constantly scrutinised on financial matters. "We want to support patient organisations but we need to know the legal and financial set-up of a patient organisation to ensure that any money given will be used appropriately, not for personal gain," he said.



The view from patient organisations (Group 1):

What do patient organisations need to know about clinical trials?

(Before addressing the questions, said rapporteur Melissa Hillier, the group spent time discussing the issue of competence, including questions such as who decides whether a patient organisation is competent and how to define competence. It also talked about education about a disease, the process of evaluation, and how to bring all partners in the committee “up to speed” to be able to discuss on an equal footing.)

1. In order to function as an advisor for pharma in all issues relating to the design and practice of clinical trials, a patient organisation needs to know a great deal about the trial – and be contacted before the trial starts. Essentially, patient organisations need information, for example on the risks and benefits of a trial, what’s involved in taking part.
2. More than this, patient organisations wish to become partners rather than simply advisors.

What do patient organisations need to know about their partners?

1. How the members of the (or any) clinical trial committee have been selected to be on that committee.
2. What drives the sponsor of the clinical trial – is it science, money or something else?
3. Whether the members of the committee are organised to hear the patient organisation and listen to its interests and needs (including disclosing conflicts of interest). That way, knowledge gaps can be identified and filled, and patient organisations will be able to give input, rather than be there as tokens.

The view from patient organisations (Group 2):

What do patient organisations need to know about clinical trials?

1. Just the one requirement: information, everything about the clinical trial – stages, infrastructure, scientific knowledge, treatment, code of conduct, resources and the future strategy (what happens after the trial). “So basically, information about involvement at every level,” said rapporteur Ariadne Stamatopoulou.

What do patient organisations need to know about their partners?

1. Outcomes: how is industry going to deal with the results of the trial. For example, partial success, negative success, and if a trial is stopped, why. Pricing after the trial – whether patients will be able to afford the medication. And so on.
2. How the other partners will benefit financially. “Just as industry want to know if they give us money, patients want to know where the money goes, what industry gets, what the researchers get, and what can be given to the patient organisation.”
3. Complete information on the legal framework regulating the clinical trial and the rights that patients have in that trial. That would include information about ethics committees



and more general laws relating to patient rights in the countries covered by the trial (“minus the jargon”). And after receiving the information, will the patient organisation have the opportunity to adapt the legal framework in a way suitable for the patients themselves?

Lina Florentin from the Hellenic Association of Medical Geneticists, Greece, wanted to know who analyses the results of a clinical trial. Is it just industry, or is there an independent assessor, she asked. Would someone in the patient group have access to the results to ensure that they are not biased?

Leandros Arvanitakis conceded that data from clinical trials have been misrepresented in the past. That’s why the major medical journal publishers formed a consortium to establish clear rules: they want to see and check the raw data before they publish the results of a trial. Regulators such as the US FDA also see the raw data before they give marketing authorisation. “So nowadays we are more secure,” he said. Ingrid Klingmann added that EudraCT would soon be publishing the results of trials. One problem is that it will only cover medicines, not devices or procedures. “But it’s a big step forward,” she said. “Everyone has recognised the need for more transparency.”

For Chrysis Michaelides, the only solution is for patient organisations themselves to organise their own networks of researchers. “Everything else is welcome,” he said, “but we have to trust our own.”

9: Action towards the ideal world: reports back from the multi-stakeholder discussions – actions to overcome the hurdles

The stakeholders were now combined into four mixed multi-stakeholder tables and – based on the ideal world and bearing in mind the results of Day Two’s breakout sessions – asked to formulate one or more action plans on how to overcome the hurdles hindering partnership between all stakeholders in clinical trials. In so doing, they were to identify the stakeholder to be responsible for the actions in their action plan – patient organisation, pharmaceutical industry, academia or regulatory authorities. “Try to negotiate,” said Cor Oosterwijk. “We have seen all kinds of hurdles, with ideas for solutions, but you cannot find solutions on your own: you have to discuss with the other stakeholders.”

Reports from the multi-stakeholder table discussions

Table 1. A database, and more

Rapporteur: Melissa Hillier, Genetic Interest Group, UK.

1. *Representativeness and credibility: a database would help*
Industry and patient organisations agree that there is an issue here. It would be useful to have a central resource for people interested in recruiting patients or patient organisations for clinical trials.
2. *Education and training: not just one company*
Patient organisations would like to get involved in clinical trials but don’t know how, or



what they should do. Who should provide the information? Industry is well placed, but information from just one company might be seen as biased. Trade bodies such as EFPIA, the European Federation of Pharmaceutical Industries and Associations, might be seen as more impartial.

3. *Clinical trials: a code of conduct*

The table felt that a standardised, clear and open code of conduct for clinical trials would help all stakeholders – perhaps developed at the EU level.

4. *Responsibility and liability: when things go wrong*

“We could have spent a day on this,” said Melissa Hillier. If a patient organisation is a partner in a trial that goes wrong, does it share liability? There should be mechanisms to minimise the downside in such an event.

Table 2. One database for all

Rapporteur: Ingrid Klingmann, EFGCP, Belgium.

1. *The Enabling of Finders Project*

The main need is for a central body where stakeholders in the clinical trials process can go for information. It would be a database, but not limited to that – an Enabling of Finders Project. The idea is ambitious, but doable.

2. *Legally obligatory*

The repository/database should be on the EU level, with a legal obligation for pharma companies, patient organisations (both individual and umbrella bodies), investigators and academic trial sites, ethics committees and human rights committees to register.

3. *Stakeholders to define*

The content of information to be entered into the database needs to be defined. It should be explanatory, exhaustive and searchable. The table proposed a committee of stakeholder representatives to plan the database. Linked to the database should be a permanent body that would develop and maintain it in a way that continuously fulfils the needs of all stakeholders and delivers real value.

4. *Who will pay for it?*

To maintain fairness and commitment, support should come from a mix of resources – some public, some from industry and some from other participants.

5. *The network*

This EU-level project is envisaged as the basis of entire network, with smaller mirror organisations in each country to ensure that coordination and collaboration between stakeholders works, and that the database is refreshed.



Table 3: From network to database

Rapporteurs: Luc Stuit, Association Française pour la Recherche sur la Trisomie 21, and Kim Wever, VSOP, the Netherlands

1. *Make the connections...*

Patient organisations in particular need a place where they can make two-way connections with other stakeholders. Given that local patient organisations often belong to national and sometimes European patient bodies, and that industry and academic bodies have similar structures, it should be feasible to create a network connecting potential partners. Such a network would provide a space for communication, for getting to know one another and for the exchange of information.

2. *...by building a database*

The database should hold sufficient information to match make those looking for each other. The idea is that the database would do the matching automatically, though how was not discussed. It should have EU funding, and possibly be attached to an existing structure, such as EudraCT. It should also give links to basic information about clinical trials in general.

3. *Down to the detail*

All stakeholders should input their details (which will be different for different stakeholders).

- a. For patient organisations, a short explanation of who they are, their position in the country, membership, funding, affiliation with others, disease area/molecule of interest. Plus what they are looking for in a contact and the input they would be willing to provide.
- b. For pharma, a list of areas the company operates in, plus the kind of patient organisations they are looking for in specific trials. And ideally – but not realistically – the molecules a company is working on.
- c. For researchers, their area of interest, the patient organisations they are looking for, and what they would want to ask the patient organisations.

Table 4: A letter to the Commission

Rapporteur: Cor Oosterwijk, VSOP, the Netherlands

1. *A good time to make a recommendation*

The European Commission is looking for advice, so give it to them. Everything the PatientPartner project does should be embedded in a letter of recommendations to the Commission, which we would hope would result in a Directive on patient partnership. First we have to work out as stakeholders what we want to say, which may require some help from the Commission.



2. *Common concerns*

The letter should start with an introduction about our common concerns, to make clear that it contains the views of all stakeholders. Its main points:

- a. A database...see below
- b. That Europe should recommend or stimulate the setting up of standard training programmes aimed not just at educating patient organisations about the technicalities of trials but also at stimulating cooperation and partnership in practice.
- c. That the Commission should recommend that stakeholders agree on standard procedures on how to work together, covering both ethical and practical aspects.
- d. That there should be guidelines on how to deal with the process after a trial ends, particularly in relation to compassionate use (for which there is no European regulation), and recommendations on how to shorten the time between the end of a trial and the drug appearing on the market.
- e. That there should also be guidelines on privacy and confidentiality for all stakeholders: for patient organisations the privacy of patients; for pharma how to deal with commercial and competition aspects; for academia those aspects relating to intellectual property and publication.
- f. That in all this the Commission should aim for a Recommendation or a Directive, but not a Regulation.

3. *The database*

It should not be top down. Instead, it should be more like Facebook, where you put your profile, say who you are and what you want, and then automatic matching takes place, with suggestions of whom to contact.

- a. Patient organisations would include their research priorities and research possibilities –their area and number of patients fulfilling prerequisites for research.
- b. There should be local information: where the patients are, where the hospitals are that might be involved in a trial.
- c. The database could also hold information on past, current and – perhaps most difficult – planned clinical trials.
- d. Nobody should be forced to put their data on the database, but it should be so attractive that patient organisations, for example, feel they need to.
- e. The running of the database might involve a large ICT partner if sufficiently interesting commercially; but it would need to be governed by a board with stakeholders, and ethics representative and an independent ombudsman to resolve possible conflicts of interest.
- f. It might be best to call it a Forum, rather than a database.



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In the discussion, Anne Micallef from the Maltese Breast Cancer Support Group wanted to know whether it was intended that individual patient organisations should contribute financially to the database. Clearly that's not possible, said Ingrid Klingmann, although she said it was an open question whether the larger umbrella patient organisations might provide some funding: "For them it would be of major interest, and they are in a position to make some contribution."

Chrysis Michaelides thought that the database would require central direction. Patient organisations might contribute in their own country to their own national network, he said, but it depends how active the national network is. On the other hand, Liliya Gentet from the French Federation of Associations of Patients with Respiratory Insufficiency or Handicap (FFAAIR) was wary of centralisation and of creating too many structures. "Bureaucracy can ruin every good initiative," she said. For Valter Dal Pos, the database had to be built from the bottom up. "Top down won't be accepted by countries and regions," he said.

Another contentious issue was whether the changes being discussed should be mentioned in the context of the currently ongoing revision of the Clinical Trials Directive. "Is it possible to make some brief comment about the way we are thinking?" asked Rod Mitchell. "Would it have value to feed that in? It can take up to ten years to get a new Regulation or Directive." Ingrid Klingmann disagreed: "Having been heavily involved in those discussions, I don't think it would be in the best interests of the project to get amalgamated into the whole Clinical Trials Directive debate, where we would not get the attention we deserve." She accepted that a link with EudraCT would bring the database into the context of that debate, "but we would have to work out how strong that link should be".

With time for discussion ending, Ingrid Klingmann asked Table 4 about its proposals in relation to access to treatment after a trial ends. How much depth had they gone into? Were they looking for new legislation, or discussion with, for example, health insurance providers? Katerina Milioni, a clinical researcher from Greece specialising in glaucoma, said they wanted to ensure that drugs continue to be provided. "The drugs should be available when the trial ends. Ethics committees and the European Commission should know that there is an opportunity here," she said. The topic was also picked up briefly in the final session by Ian Ellul from Malta, who described earlier access to compassionate use programmes as "an obtainable objective".

10: Final plenary session: summary and action plan to go forward to the final PatientPartner workshop

After two days of discussion and prioritisation, and with so many common themes and ideas in the individual action plans that came from the breakout groups, the main lines of action had already been drawn up. Instead of repetition, the final plenary session moved seamlessly towards ways of improving the regional and national structures of patient organisations and communications between them. At the end, Ingrid Klingmann summarised the core recommendations to go forward to the final PatientPartner workshop. But first, delegates had some words to say on ethics.



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Talking about ethics

Luc Stuit noted that the proposed database was light on ethics. We will also need to regulate ourselves, he said, which is an issue of ethics. Ariadne Hager-Theodorides, herself a member of Greece's National Bioethics Commission, suggested that ethics committees could be a key point in the collection of ethics information. Meanwhile, Valter Dal Pos warned of the importance of language in ethics. "I don't feel competent to talk about ethics in another language," he said. "There should be an area where ethics material can be translated properly." This needs to be built into the database, he said.

At Ingrid Klingmann's suggestion, it was agreed to propose that all delegates, in their own area of indication, will try to bring different patient organisations together to figure out what type of national umbrella organisation or network can be formed to enable everyone to talk to each other. "Just a couple of phone calls," she said. "That's something that can be started tomorrow – and it would be a big step towards bringing transparency to this ocean of associations."

Coming together: from the bottom up

Matteo Schwarz kicked off the discussion on the formation of umbrella organisations. His starting point was that the database must be built from the bottom up (certainly during the registration phase, said Joseph Busuttill). "The requirements for participating should not be very strict in the first phase, because otherwise some associations might be excluded." But, he said, since we know that there are thousands of patient organisations, and we need to have some order, "we should strongly encourage associations working in the same disease area to form some kind of national organisation to sort out what goes into the database".

Start with trials

Rod Mitchell pointed out that it might be helpful to restrict the umbrella groups to cooperation on clinical trials – since patient organisations sometimes come together anyway to talk about trials but rarely to discuss other matters. It was not that he was against patient organisations coming together, but that "if that doesn't work then at least they could collaborate in the clinical trials area. Yes, said Matteo Schwarz, that would be a good start; then if they get together for a clinical trial, they might think about collaborating in other matters.

Ingrid Klingmann agreed: a stepwise approach would work. Cor Oosterwijk also believed this kind of approach could be an option for industry, and also for academic researchers. Meanwhile, Luc Stuit pointed out that sometimes historical reasons get in the way of ideal cooperations, but that a common subject such as clinical trials could be the way to start common working. "The European Union started with coal and steel," he said. "It didn't go straight to the euro. So clinical trials could be our coal and steel."

Going national

Ingrid Klingmann asked whether it might be possible, at the national level, for patient organisations to work not just with others in their same indication but more generally – initiating a national dialogue or workshops in a country to find common denominators and projects. The response was enthusiastic.



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From Italy, Valter Dal Pos said he would try to arrange a conference in northern Italy. "It's a big job for a small organisation, but I will have a go at it," he said. From Malta, Joseph Busuttill said that he and Pierre Mallia will try to gather together all the patient organisations in their country and establish a federation. Ingrid Klingmann added that the pharma industry organisation in Spain is planning a workshop with patient organisations to discuss the same issues as the Athens workshop.

Industry could help with the funding of these workshops, she said, but to ensure neutrality it is important also to invoice representatives from ethics committees and the regulators. Another good way of obtaining funding is to look at European programmes such as Europe for Citizens, said Chrysis Michaelides.

Keep talking

The discussion now shifted towards communications. Activities such as the federation of patient organisations are "popping up in different countries", said Ingrid Klingmann. "It is important that everyone sees what can be and is being done. Nobody is alone."

Yes, said Chrysis Michaelides, it is good to know what other people are working on. "We are working on a project with nurses and carers," he said. "When I get back to Cyprus I will send you all an invitation to take part. You tell us what you are doing and we will support you. We need to keep communicating after the workshop."

Kim Wever said that a newsletter has been on PatientPartner's wish list, but that the project was waiting for the Athens workshop to take place. "We will get that newsletter to you," she said. Ingrid Klingmann pointed out that the newsletter "can only be as informative as the information you provide". It would also be helpful to know about useful treatments, said Luc Stuit.

The new European Network of Patients Partnering in Clinical Research, EN-PCR, will also enable patient organisations to get in touch with each other and talk about what they are doing. "This could help with the drive to form federations," she said.

She described the EN-PCR as "a virtual forum in which we hope to give patient organisations opportunities to discuss a number of aspects of clinical trials, including discussing further the idea of a database". The network will come up with a list of discussion topics and start a mailing group. "We will use the outcomes of the discussion to build on the information and results from the workshops," she said. "Hopefully in the future it will develop into a one-stop shop for match-making with industry and researchers." But for now the EN-PCR is just for patient organisations.

Alberto Morales from the Spanish Glycogen Storage Disease Patient Association (AEEG) stressed that information must be more accessible. "Most of our organisations are looking for information," he said. "If information is easy to access it is more easy to make contact with others."

An umbrella, not a shield

A potential problem with umbrella organisations is that they can be exclusive. In some countries with official federations the government will not talk to other organisations, said Chrysis Michaelides, although the European Union's encouragement for open coordination means they



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now have to take into account the views of others. Networks, he said, will mean that governments will have to keep in touch with more patient organisations.

Networks also make you more “findable”, said Kim Wever. Marianne Michailidou from the European Social Forum of Cyprus agreed, citing Eurordis, the European Organisation for Rare Diseases, as a good way of finding people. But they cannot do everything. “You might need an umbrella organisation for, say, regulatory issues, but still need the local organisation for looking after patients,” said Wever.

Alberto Morales sounded a note of caution. “The information that goes to the umbrella organisation doesn’t necessarily reach all the members of that organisation. Too many levels of organisation can hinder communication,” he said. “I’m not against umbrella organisations, but they aren’t the only voice for patient organisations.”

From Italy, Valter Dal Pos said the experience of families varies so greatly and is so difficult to communicate that it is hard to form an umbrella organisation for rare diseases in his country. “Umbrella organisations should develop around a project, but exclude other factors. Associations for everything are not good.”

It’s a complex area. Luc Stuit said that his organisation sometimes finds it easier to cooperate with others at the European level, rather than at the local or national level where they have different ways of working. And in France it seems to be easier to get together at the European level than within the country.

Clearly, one size does not fit all, as Ingrid Klingmann said. “How to structure collaborations with different patient organisations is a delicate balance. It’s different in rare and in common indications, and sometimes the disease itself hinders verbal communication or physical meetings. All that has to be taken into account nationally and internationally.”

And in summary...

The clear common topic to emerge from the workshop is that before we can start working together we need to find out about each other, said Ingrid Klingmann. That all the breakout groups came up with this common approach without prompting from the facilitators shows that this is a strong need, she said. She summed up the recommendations from the workshop thus:

1. *The database for stakeholders in clinical trials (otherwise known as the Enabling of Finders Project)*
 - a. It should be a database for all stakeholders, with structured input from all groups.
 - b. It should be managed by an independent expert group with equal representation from all stakeholder groups.
 - c. It should be enabled from a European level – we can achieve more in a shorter period of time if we do it through Europe.
 - d. It should be established within the framework of strong European legislation to ensure that ultimately it will happen.



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- e. We should not wait for funding from Europe, but seek to establish a fair and collaborative solution.
- f. It will have to be built via a bottom-up approach, starting with small steps and at national levels.
- g. Language must be adapted to the needs of the users.

Such a database would be an “excellent signal” that we can have such a partnership in the world of clinical research, said Ingrid Klingmann.

2. *A letter to the Commission with as its main points:*

- a. The need for the database
- b. That Europe should recommend or stimulate the setting up of standard training programmes aimed at educating patient organisations about the technicalities of trials and stimulating cooperation and partnership in practice.
- c. That the Commission should recommend that stakeholders agree on standard procedures on how to work together, covering both ethical and practical aspects.
- d. That there should be guidelines on how to deal with the process after a trial ends, particularly in relation to compassionate use, and recommendations on how to speed up the time between the end of a trial and the drug appearing on the market.
- e. That there should also be guidelines on privacy and confidentiality for all stakeholders: for patient organisations the privacy of patients; for pharma how to deal with commercial and competition aspects; for academia those aspects relating to intellectual property and publication.

3. *Encouragement for networking and the formation of umbrella patient organisations:*

- a. Bringing together patient organisations on a per-indication basis, but also nationally and regionally.

4. *A heightened stress on communication through:*

- a. Organising national workshops to bring patient organisations together.
- b. Encouraging communication at all levels – between umbrella organisations and their constituent groups, but also between PatientPartner and individual patient organisations.
- c. Using the EN-PCR network and newsletter.

11: Next steps

Joseph Busuttill wanted to know whether delegates would be informed about what happened in the other workshops. “And following that, will PatientPartner be combining all the ideas from the three workshops and letting delegates know the outcome of all these events?” he asked. Yes, and



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yes, said Ingrid Klingmann. The reports will not just be made public, they will be sent to every delegate.

Equally, she said, it would be good to hear before the autumn workshop of progress in creating umbrella patient organisations.

There would be three “final outcomes” of the project, said Kim Wever: a Patient Organisation Guide to help patients to become partners in clinical trials; a Guide for Investigators and Pharma to help them to partner with patient organisations; and a recommendation to the European Commission for further action to aid the development of partnership.

All delegates were invited to come to the final PatientPartner workshop in Brussels this September, which will bring together and reach a consensus on the proposals from all three regional workshops.

/ends