10 YEARS OF

EGAN-ROCHE PARTNERSHIP

AN OVERVIEW

THE PARTNERSHIP FORMULA

About EGAN

EGAN is the 'Patients Network for Medical Research and Health (EGAN)', an alliance of both national genetic alliances and European disease specific patient organisations with a special interest in genetics, genomics and biotechnology. Especially, but not only, genetic disorders are represented within EGAN. EGAN is working for a voice in research and health policy and seeks a world in which genetic and other serious diseases are understood, effectively treated, prevented and the people affected supported

About Roche

As a research-focused healthcare company, Roche discovers, develops and provides innovative diagnostic and therapeutic products and services that deliver significant benefits to patients and healthcare professionals – from early detection and prevention of diseases to diagnosis, treatment, and treatment monitoring. Today, Roche employs more than 80,000 people and sells its products in more than 150 countries. Roche ranks among the world's leading healthcare companies and has two strong core businesses: diagnostics and pharmaceuticals.

The EGAN-Roche working party

The goal of the Working Party is to work on topics of common interest. This has meant the development and dissemination of accurate, clear and comprehensible information, development of standards of good practice in patient/industry relationships and improvement of effective communication and recruitment to clinical trials.

Activities include a yearly two-day meeting which focuses on common issues in the biomedical and pharmaceutical research and policy field, to which a broad spectrum of European patient representatives, Roche representatives and other stakeholders are invited. In between these meetings, the EGAN-Roche working group elaborates on the priorities and actions that are commonly identified during the preceding meeting.

The partnership provides a solid foundation for open discussion where dialogue is not limited to sharing common views, and where divergent opinions can be exchanged and further explored. It has developed information and educational materials for EGAN, but also shaped Roche's internal policy on issues close to patients.

Principles of Cooperation between EGAN and Roche

- The EGAN/Roche relationship shall be characterised by mutual respect, trust, genuineness and commitment.
- The partners consider each other to be of equal value in the partnership.
- The objectives and scope of the partnership shall be transparent to third parties and the public.

Front page: participants at the 2007 Workshop

Signing of the Principles of Cooperation on September 8, 2006. From left to right: Silvia Matile-Steiner (Roche), Klaus Lindpaintner (Roche), Cor Oosterwijk (EGAN), Alastair Kent (EGAN), Ysbrand Poortman (EGAN)

10 YEARS

The initiators of the Roche-EGAN working party tell the story of how it all began in 2004, share their personal perspectives on its value and their outlook for the future.

Silvia Matile-Steiner, Head Government/Public Affairs at corporate level at F. Hoffmann-La Roche headquarters (-2011)

Alastair Kent, President of EGAN and Director of Genetic Alliance UK

How it all started in 2004

Silvia: “Industry and patient representatives used to meet under the roof of EFPIA, at European level, in the so-called Think Tank meetings, but also on other occasions, e.g. at EPPOSI. There, I got to know Ysbrand Poortman, Cees Smit, Alastair Kent and others. We developed a common sympathy and, over time, we started to discuss possibilities of organising a workshop at Roche.”

Silvia explains that the parties soon saw the need for a regular and in-depth get-together with more consistent meetings, also open for representatives from other patient organisations. That was the start of the cooperation between EGAN and Roche.

“The EGAN workshops were probably the most rewarding work in my job,” she says. “I loved doing this; the contacts, the content, the dialogue.”

Alastair: “The EFPA Think Tank established issues on common grounds that led to further development of relationships between patient organisations and industry and also a number of one-on-one partnerships where you felt there was empathy or a kind of sympathy between the characters of the people in patients’ organisations and pharma companies. Between EGAN and Roche there was both an overlapping of interests and a click on a personal level. EGAN was interested in contacts with Roche especially because of their diagnostics. And Silvia was very open to the idea of partnership: she had insight into the nature of the relationship that had to be formed in order to be productive.”

One of the first partnerships of its kind

Alastair: “At that time there were quite a lot of people in the pharma industry and in the public policy arena who didn’t see patients as a potential partner for exploring common strategic issues. It was a coalescing of feelings about partnership. The 2006 agreement was one of the first bipartite relationships that were formalised by a written agreement. **At that time it was relatively unusual to have that kind of formal recognition.** I am not aware of any other such agreement.”

Alastair Kent at the 2007 Workshop

“Many people recognize the legitimacy of patient organisations and industry interacting in a strategic way. There are obviously those who think you should have no contact with industry at all, and if you do you sell out. These are the people who always thought that and always think that and will not change their opinion.”

“There has been a maturing of the relationship and activities like the partnership have helped. It gives people from the industry the opportunity to meet people from patient organisations and see that these are not just naïve idealists, but people that are capable of strategic thinking. And equally the representatives of patient organisations meet the drivers of the industry and see these are not only evil capitalists.”

The value of the workshops

Alastair was interviewed for the internal Roche publication myRoche in 2012 and had the following comments on the Roche/EGAN cooperation. “It is important that we can have a relationship that allows for as full disclosure as possible with mutual respect and the understanding that either party won’t misuse information. In terms of this particular partnership, we have achieved that kind of shared understanding of what is and what is not feasible and the **mature relationship that allows us to differ and reflect different priorities without falling out**.”

Silvia: “Roche participants in the workshops were highly motivated and appreciated the opportunity to have the dialogue with patient representatives. The quality of the workshops has always been quite good. Strategy development is more delicate. We discussed strategic issues, such as how to address public mistrust, but it is more difficult to realise the ideas that are brought up. The public often thinks that it is bad when patient organisations speak with industry. So far, an ideal solution how to address this could not be found.”

Alastair on the value of the partnership: “Building relationships, having the opportunity to build understanding, examining issues in more depth, strategically rather than reactively. The bringing in of external speakers - economics, academics, politicians – in a safe environment where they are not going to be attacked, but give insight into the way they will work.”

Silvia:” I have the feeling that indeed the initial aim of increasing communication and understanding has been realised. We had a very open dialogue. We had a lot of European representatives, some of them came from the very first beginning, some jumped in at the second or third workshop. This continuity is important. At a certain moment we especially opened the workshops to representatives from Eastern Europe. They did not work on a European level, but in one of the countries in Eastern Europe (e.g. Bulgaria, Poland). We found it important for them to intensify their contacts with others and to benefit from the experience of their colleagues.”

Transparency and disseminating the outcomes

Silvia: “I feel that we had full transparency. We spoke about our cooperation at the EFPIA Think Tank meetings, so industry and patients were aware of that. Patient representatives had the opportunity to join the workshops. Moreover, the brochures are public, everyone can download them from various websites and use them, even translate them into other languages with EGAN’s agreement.”

Silvia Matile-Steiner at the 2007 Workshop

Alastair: “The aim is to create a shared vision. It is not to have a highly visible public profile. It is to provide an opportunity for people to take time out and think about issues that they do not have time in their daily jobs to get into. They can meet with people working in the same arena; it informs their opinions and their actions. It keeps them from being too narrow in their thinking.”

Silvia: “Therefore, we kept it low-key. What was discussed was according to Chatham House Rules, which encourages free discussion, so we worded results carefully. The patient organisations mentioned the workshop in some annual reports and on their websites, and it was also published in the Roche annual report in the chapter on sustainability. In the Roche Newspaper, which is public, we had an article for each workshop, together with interviews done with Alastair, others and myself.”

The future

Alastair: “I hope the workshops will continue. I think it is a very useful and enjoyable forum with a constructive discussion about overarching themes. That is something you don’t find elsewhere. When you meet these people in other contexts, it is always about a specific action to be taken now, always focussed on the short term. The advantage of the workshops is that they have a longer-term perspective, they provide the opportunity to build relationships that are necessary to work in an ‘action now’ situation. You get to know people and you know you can trust them – not for nothing ‘trust and transparency’ are the themes of the coming workshop.”

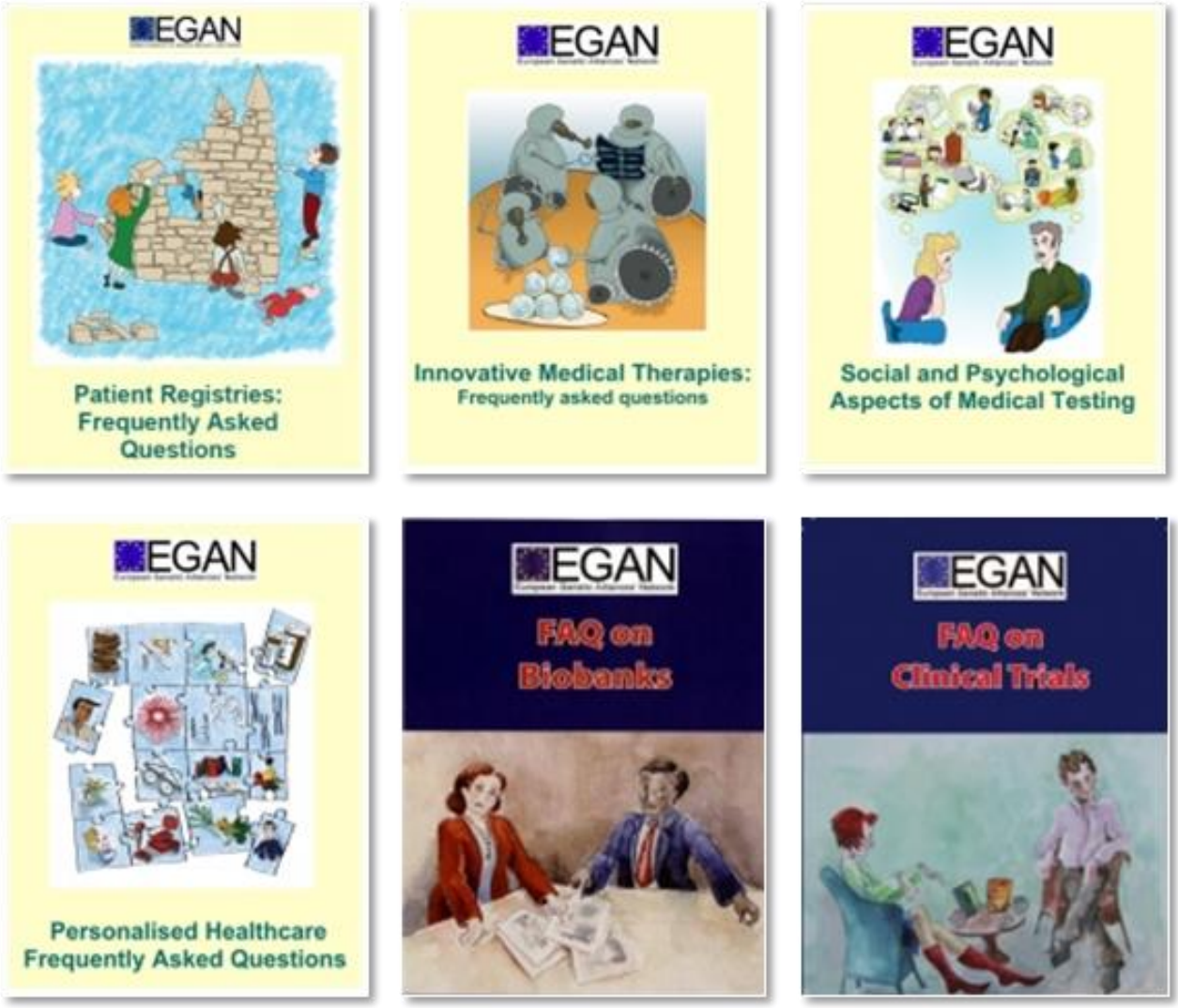
Nathalie Stieger, Head Government Affairs (since 2011), F. Hoffmann-La Roche headquarters: “EGAN and other patient organisations and stakeholders that have contributed over the years are highly valued partners to Roche. Our dialogue and interaction will continue to take place on common themes in many different ways and platforms. As we can see from the common themes, there is still a lot for the industry and patients to discuss and to do. Therefore, partnerships such as the Roche-EGAN working party will continue to grow even more in importance and will need to adapt to new arising topics and needs.”

OUTPUTS

FAQs for a lay audience

EGAN and Roche saw a need early on for a series of FAQs on healthcare topics targeted at a lay audience. The process of creating the FAQs is unique in its kind. Firstly EGAN identified the questions which were frequently asked by patients, then specialists from Roche were asked to supply answers to these questions. EGAN finally ensured that everything was understandable for those without a medical background.

The FAQs were posted on the public website biomedinvo4all and translated to several other languages, in addition to English**.**



Layperson booklets in the form of FAQs resulting of the collaboration between EGAN and Roche

Making 'informed consent' forms for clinical trials more user-friendly

Not only FAQs were produced to make complex topics understandable for a lay audience. In 2008, Roche worked on a more reader friendly version of the company's informed consent forms, through which participants in clinical trials are informed about and agree to participate in the trial.

EGAN acted as an advisory body to improve these forms that every participant in a clinical trial has to sign. The original ones were hard to understand without a medical background, so they were re-written with the goal of translating technical language into something that patients could easily understand. By using the revised forms, potential clinical trial participants were able to make a well-informed decision and investigators could use the forms to educate potential participants in a study. The improved version was subsequently used in Roche's clinical trials.

Annual workshops as informal platforms for education and exchange

Aims of the EGAN-Roche annual workshops

- Increase communication and understanding between patient leaders and industry experts
- Discuss topics of mutual interest in order to achieve a good level of knowledge and improve common understanding of these topics
- Foster dialogue between patients and industry on new developments in healthcare
- Highlight innovative healthcare solutions
- Focus on new/innovative fields of interests
- Include strategy development for the subject at stage

Annual workshop themes & attendees

2006	Clinical Trials, Personalised Medicine, Diagnostics (24)
2007	Clinical Trials, Biobanks, Paediatric Medicines (20)
2008	Exploratory Development and Clinical Research (29)
2009	Health Technology Assessment and Personalised Healthcare (29)
2010	'How New Therapies Emerge' and 'Striking the Balance' (29)
2011	From Research to Clinical Practice (36)
2012	Data sharing & Therapy development: Possibilities and Pitfalls (43)
2013	In Times of Crisis: Sustainable Healthcare Systems and the Role of Patient Groups (33)
2014	Trust and transparency (33)

COMMON THEMES

A snapshot of the key common themes – and related discussions and recommendations – is presented below. Many of these themes were the subject of further cooperation and/or a topic of one of the many FAQs for lay persons produced jointly by Roche and EGAN.

Clinical Trials

The EGAN/Roche working party has discussed clinical trials on several occasions.

One focus was the question of how to make information on clinical trials available. This information helps patients enrol in a clinical trial, enhances accountability and transparency, and provides access to results in a comprehensive and objective manner. However, there are challenges as well. For example, content requirements may stifle innovation due to disclosure of competitive sensitive information.

In 2011, the EGAN/Roche working party issued recommendation on how to improve the long process from basic research to clinical practice, including better patient involvement. One important aspect of these was the acknowledgement and use of “soft endpoints” in clinical trials, such as Quality of Life.

In later years, discussions revolved around the need to change the current investigator centric model for clinical trials into a new patient centric model, and explored how emerging technologies such as social media can be used to broaden patient access to clinical trials and enhance recruitment and participation. Clearer and more comprehensive information about the trial, as well as health literacy and education, were mentioned as key tools to ensure that patients and patient representatives can use the digital opportunities to their advantage.

A recommendation throughout the ten years has been that stakeholder cooperation should be promoted very early on in the research process, bringing together patients and those who develop medicines to promote a better understanding of patient needs as goals of the research.

Animal research

Both in the 2009 and 2010 Workshops, animal research was reviewed from both sides: Silvia Matile-Steiner gave information on the activities at Roche and in the pharma industry, while Nick Meade told about the UK Genetic Interest Group (GIG) policy on research involving animals. GIG published a position paper saying a.o. ‘The use of animals in medical research is a vital, legally required, stage in the development of treatments for patients with unmet medical needs’.

Personalised medicine

The new paradigm of personalised medicine/personalised healthcare has been revisited several times by EGAN and Roche.

Personalised medicine is about the discovery and development of pharmaceuticals and diagnostics that better account for human variation and for the diverse molecular basis of disease. The idea of personalised medicine is new and old at the same time. It has been known for a long time that the same therapy has different effects on seemingly similar individuals. New is that fairly advanced tools now allow for diagnosing the biological differences between people. There are already examples of proven biological differences (a.o. breast cancer, metabolic differences, rheumatoid arthritis). Research requires access to tissue and blood samples - which implies that advances are especially expected in common diseases where disease-relevant tissue is more easily obtained.

In 2006, the **ethical dimensions of personalised medicine** in relation to genetic testing were addressed, as well as the awareness level of healthcare professionals about personalised medicine solutions and their abilities to use them. Professional education and training were seen as necessities to introduce new diagnostic techniques.

In 2014, these concerns still seem to be valid. High expectations ride on personalised medicine, yet

challenges remain when it comes to bringing the new paradigm into clinical practice. Patient organisations worry are about where to draw the line between patients who receive the treatment and patients who don't. Finding the right balance will be a challenge for healthcare systems, and it is likely that in the end, decisions will have to be made on a case-by-case basis.

Biobanks

In the past decade, developments in the field of genomics and in bio-informatics have increased our knowledge on the interplay between genes, environment, and lifestyle factors. To get a better understanding of this complex interaction, researchers need to examine large quantities of data and human specimens.

At present biological human materials and data are stored in a large number of Biobanks all over the world. These Biobanks contain tissue samples and/or bodily fluids and the data associated with those materials. Decisions about the collection, storing, processing and distribution of material and data require input from all stakeholders. The associated issues have been a recurring topic of discussion in the Roche/EGAN working party.

Data sharing & registries

Questions of data generation, data sharing and data management will come up repeatedly over the next years, particularly in the course of the ongoing revision of European legislation. Central to creating a successful and a proportionate regulatory framework is an understanding for when it is or is not appropriate to share data. Under what circumstances can different interested parties legitimately expect to have access to particular data sets?

It is important to be able to capture data generated by patients. But it is also important for patients to understand the process by which that data is turned into interventions. Patients are interested in knowing what will happen with their data, and along with other aspects, the information may encourage or prevent them from contributing.

On a related note, the EGAN/Roche working party issued recommendations in 2012 on the purpose of a registry (i.e. a database where patient characteristics is stored), its content, standardization, how to ensure the quality of its data, access to and understanding of the data, and the funding and support of registries.

Health Technology Assessment (HTA)

Health Technology Assessment is a multidisciplinary field that addresses the health impacts of technology, considering its specific healthcare context as well as available alternatives. Contextual factors addressed by HTA include economic, organisational, social, and ethical impacts. Health technologies include pharmaceuticals, devices, diagnostics and treatments, and other clinical, public health, and organisational interventions.

The EGAN/Roche working party issued recommendations on HTA in 2013 which highlighted the need for patient input to define the value of healthcare interventions. Patients need to be appropriately trained and informed to take part in these discussions in an effective way. All parties must be aware of the challenge that different terminologies are used by HTA experts and patients, and make an effort to communicate in a clear way. Data need to be gathered in the right way and be presented early enough to be considered in the HTA process.

CONTINUING THE DISCUSSIONS

Patient organisations such as EGAN are important partners for Roche. Representing the patient voice, these organisations help Roche understand what it is like to live with a disease, the challenges patients and their families face, and the role that diagnostics and treatments play in managing disease. This guides Roche in developing new medicines and in clinical trial programmes, in seeking regulatory and reimbursement approvals, and providing patient support.

As patient organisations represent patient views on issues surrounding healthcare, they help shape the current and future healthcare environment by making their collective voices heard.

A new era for communication
Since 2006 a lot has changed: patients are more educated, and the internet provides them with better means to interact. Social media makes a big difference. In parallel with this development, several new face-to-face meetings and platforms for patients and the industry have been created where discussions can take place on specific topics.

Roche's and EGAN's dialogue and interaction will continue to take place on common themes in many different ways and platforms. As we can see from the common themes, there is still a lot for the industry and patients to discuss and to do.

Therefore partnerships such as the Roche-EGAN working party will continue to grow even more in importance while simultaneously having to adapt to newly arising topics and needs.

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Selected participants at the 2012 Workshop