

WORKING TOGETHER WITH PATIENT GROUPS

September 2017

Developed by the EFPIA Patient Think Tank



FOREWORD

Europe is facing significant healthcare challenges due to an ageing population and increased prevalence of chronic disease and multi-morbidities. Equitable access is a major issue for many patients.

In the past, industry, academia, healthcare professionals, regulators, and patient organisations have largely worked in silos. In practice, many decisions about patients' care, medical research, health information and service design were taken without meaningful patient involvement. This led to inefficiencies and low value in process and outcomes.

But this is starting to change. In recent years, many companies have developed new ways to incorporate patient insights and to collaborate with patients and patient organisations in a transparent and ethical way. This has led to better trials, better engagement, better communication throughout the entire life cycle of medicines – and ultimately better patient outcomes. This development is not yet universal but the direction of travel is there. The industry and patient organisations are committed to improving collaboration and building trust across the entire spectrum of stakeholders.

This requires us to recognize the vital role that patient organisations and patient communities play in sharing knowledge as equal and valued partners.

Alongside leadership from strong patient organisations, patients are coming together online to share information and experiences concerning their diseases and conditions. Capturing these insights and using this data to inform medical research could help to deliver more patient centered treatments and services.

Advances in data capture and analysis techniques are leading to new areas of research and a better understanding of what really delivers improved patient outcomes. Yet, the use of health data is a sensitive topic. It is imperative that stakeholders work together to ensure that the potential of health data can be unlocked in a manner that promotes patient confidence and supports data security.

The evolution in patient engagement is matched by the rapid progression of the science that underpins research and development of medicines. This progress allows for more personalised medicines that target individual patient needs. In order to support this transition, all stakeholders must explore new models of engagement between patients, healthcare providers and industry.

It is clear that to meet this end, the health sector must place a greater emphasis on collaboration and new ways of working. *This must form the basis for building a common vision of a healthier future for all Europeans.*

Stefan Oschmann
President
EFPIA

Nicola Bedlington
Secretary General
European Patients Forum

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1. PURPOSE OF THE DOCUMENT

The aim of this document is to underline the rationale for interactions between the pharmaceutical industry and Patient Organisations¹, suggest the principles on which these interactions should be based, outline the points of collaboration through the life cycle of a medicine, discuss some of the challenges and potential solutions to interact as well as providing a list of resources to support meaningful/appropriate collaboration.

This document does not relate to relationships with *individual* patients however it is designed to provide support to all stakeholders considering how best to engage in collaborative efforts to improve the lives of patients and could work as a best practices' model for other organisations.

Since the EFPIA Code on Relationships between the Pharmaceutical Industry and Patient Organisation (PO Code) was developed, there has been a significant shift in the world and encouragement to do so for more collaboration between consumers, patients and the industry. This paper is an additional point of reference to guide these interactions, and to supplement the PO code. This document is not intended to be an exhaustive document but rather a useful reference point.

2. HOW THIS DOCUMENT WAS PRODUCED?

This document was co-created by representatives of Patient Organisations and the research-based pharmaceutical industry through the EFPIA Patient Think Tank² with support from EFPIA's Ethics and Compliance Committee.

3. WHY DO PATIENT ORGANISATIONS AND INDUSTRY NEED TO INTERACT?

All partners in the healthcare equation agree that the patient should be at the heart of healthcare, from, prevention and awareness, through research and development, regulatory and Health Technology Assessment (HTA) processes, to service design and outcomes measurement.

Medicines³ are some of the most powerful tools in treating and curing disease. Their use, efficacy and impact are often central to the patient pathway, experience and outcomes. In that context, developing patient centered policies, gaining patients' insight in to the development and use of medicines and ensuring that relationships, collaboration and partnerships are focused on benefit to patients, are all key drivers in putting the patient at the centre of healthcare.

The WHO [Declaration of Alma-Ata](#) (September/1978) underscored that people have the right and duty to participate individually and collectively in the planning and implementation of their health care. That means not only in healthcare delivery but in how medicines are researched, developed and introduced.



ENGAGING PATIENTS COLLECTIVELY IN HEALTH POLICY DECISION MAKING IS THE RIGHT WAY FORWARD TO ENSURE THAT THOSE POLICIES AND PRACTICES ACTUALLY REFLECT REAL LIFE NEEDS AND PREFERENCES.

NICOLA BEDLINGTON, EPF

¹ Patient Organisation are defined as not-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers (EFPIA Code on practice on relationships between the pharmaceutical industry and patient organisations – Scope)

² More information on the EFPIA Patient Think Tank, including meeting reports can be accessed at www.efpia.eu/relationships-codes/patient-organisations/the-patient-think-tank/

³ "Medicines" refers to "Medicinal products" with the meaning set forth in Article 1 of the Directive 2001/83/EC

Patients with knowledge or experience of condition will be able to provide true picture of what it is like to live with a specific condition, how care is delivered, how that impacts on them, their careers and families and how medicines and other treatments can change their quality of life and meet their needs.

Listening to patient experiences, patient challenges and exchanging insights can shape future of medical research and disease management to more adequately address the unmet needs of patients. And it is only through open and transparent dialogue between patients and industry that we can ensure that the patient perspective becomes an integral part of how medicines are researched, developed and delivered to patients. Appropriate inclusion has the potential to co-create and co-develop better health care management and patient outcomes, delivering greater efficiencies in healthcare utilization.



OCCASIONALLY, ALL CITIZENS HAVE TO MAKE IMPORTANT HEALTH DECISIONS THAT AFFECT HEALTH OUTCOMES. STRATEGIES TO SUPPORT PATIENT EDUCATION AND ENGAGEMENT SHOULD THEREFORE BE A FUNDAMENTAL PLANK OF HEALTH POLICY. ALSO, PATIENTS CAN PLAY AN IMPORTANT ROLE IN UNDERSTANDING THE CAUSES OF ILLNESS, PROTECTING THEIR HEALTH AND TAKING APPROPRIATE ACTION, CHOOSING APPROPRIATE TREATMENTS FOR ACUTE EPISODES OF ILL HEALTH, AND MANAGING CHRONIC ILLNESS. THESE ROLES MUST BE RECOGNIZED AND SUPPORTED.

WORLD HEALTH ORGANISATION⁴

⁴ <http://www.who.int/management/general/decisionmaking/WhereArePatientsinDecisionMaking.pdf>

4. PRINCIPLES FOR ENGAGEMENT BETWEEN PATIENT ORGANISATIONS AND THE RESEARCH-BASED PHARMACEUTICAL INDUSTRY

Patient representation is dynamic and evolving rapidly, views are expressed as individuals, through Patient Organisations and through more informal online communities. Although pharmaceutical companies may approach healthcare challenges from a different angle to Patient Organisations, and are considered commercially or financially incentivized, the exchange of ideas within an ethical framework and without compromising independence, is a key vehicle to ensure patients have a voice in the development of the treatments.

Not only is the information exchange critical but also how these relationships are managed and the foundations on which they are built that are crucially important to provide a strong basis for positive collaboration in the future. There are a number of principles that provide a platform for appropriate engagement:



CLARITY OF PURPOSE

Collaboration between pharmaceutical companies and Patient Organisations fulfill a legitimate need for interactions identified in advance. Pharmaceutical companies and Patient Organisations should be clear about the purpose of the engagement and the desired outcomes.



TRANSPARENCY

Transparency of the aims and objectives of any collaboration builds trust and allows for independent external scrutiny. All financial relationships should be transparent and any compensation to Patient Organisations' representative should be proportional and commensurate with experience, expertise and the time invested.



INDEPENDENCE

It is the independence of Patient Organisations, in all aspects of their decision-making, development of policies and external communications that helps to ensure credibility and patient confidence. Funding from a wide range of sources is preferable and this can include provision of statutory funding by the EU and member state bodies.



RESPECT

In any collaboration, stakeholders bring their own perspectives, skills and experience. Collaboration should be based on mutual respect, prioritizing long-term commitment over short-term needs and valuing each other's contribution.

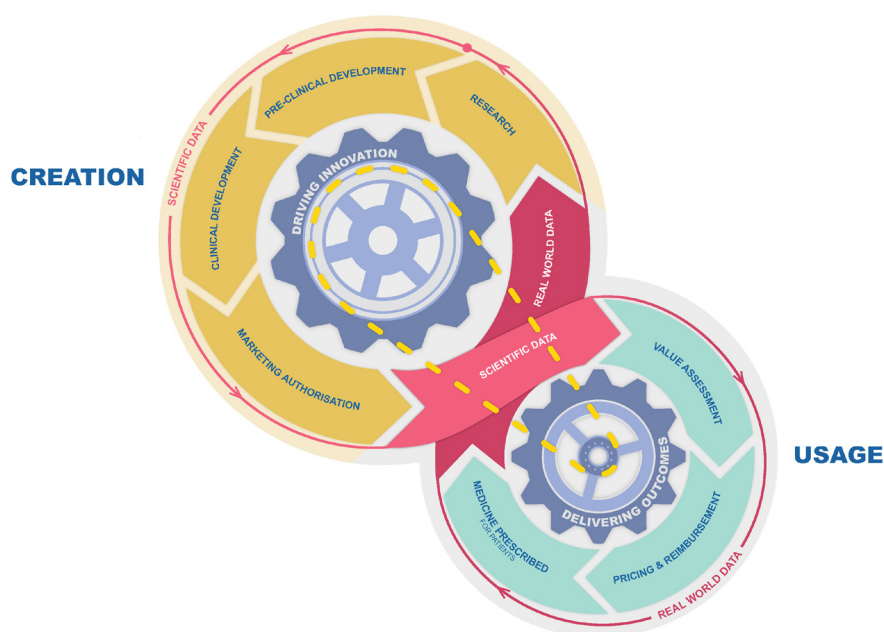


NON-INTERFERENCE

This document does not address, nor would suggest any interference in the critically important doctor-patient or healthcare professional (HCP) - patient relationship.

5. VALUE TO PATIENT ORGANISATIONS ENGAGING ACROSS THE LIFE CYCLE OF A MEDICINE

Patient engagement is critical across the life cycle of a medicine. In some areas of activity such as research, disease awareness or clinical development, this is direct engagement between industry and Patient Organisations. In other areas, such as regulatory or HTA processes there is a need for information exchange between companies and Patient Organisations to build understanding of the impact and clinical value of a new medicine, however direct engagement in the process is between Patient Organisations and regulators or HTA bodies. The section below outlines some of the key potential areas of activity and input for Patient Organisations over the life cycle of a medicine. Practical examples of industry, Patient Organisations and healthcare system collaboration are featured in the [EFPIA Health Collaboration Guide](#).



PROVIDING INFORMATION TO INDIVIDUAL PATIENTS

The article 88 of the Directive 2001/83/EC⁵ includes a requirement that Member States prohibit the advertising to the general public of prescription only medicinal products, however the article 86 allows companies to provide non-promotional information on human health and diseases.

Where educational programs are considered, Patient Organisations can/may collaborate with Industry to co-create, co-educate within requirements of relevant laws and codes of conduct.

Concerning clinical trials data disclosure, trials conducted in the EU need to be registered with the EudraCT database. Since 2014, a summary of results of phase 2-4 studies that ended must also be submitted within 12 months of their end to the Clinical Trials Register, irrespective of the result (and within 6 months for paediatric trials).

The new EU Clinical Trials Regulation requires the submission of summary results and clinical study reports to be made public.

Data from clinical trials can also be obtained for products, which have been approved by the European Medicines Agency (through the centralised approval procedure after the beginning of 2015).

Every medicine pack includes a patient information leaflet (PIL), which provides information on using the medicine. PILs are required by the regulator and are based on the Summaries of Product Characteristics (SPCs) that are a

⁵ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF>

description of a medicinal product's properties and the conditions attached to its use. Companies may also provide factual, non-promotional, evidence based answers to patients' specific questions on an individual medicine.

RESEARCH AND CLINICAL DEVELOPMENT

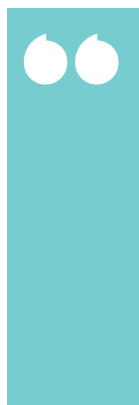
Patient Organisations' input provides researchers with insights into the challenges of living with a disease, enabling medicines manufacturers to incorporate patient feedback directly into their R&D processes, aims and objectives, leading to better treatments. Engaging with the research process also helps patients to better understand the benefits and risks of medicines and treatments, which may translate into better health outcomes. For more information on patient involvement in the research and development process, please see section 7.

CLINICAL TRIALS

Patient Organisations may take part in clinical development through a variety of channels, working with regulatory authorities, ethics committees, investigators, and industry. They may also contribute to study design – which should reflect their needs, and study literature – including the simplification of informed consent forms and the development of [layperson summaries](#) which are designed to inform research participants about the trial in which they participated and recognize the patient's contribution and their role as partners in research. They may also provide input into recruitment and retention, helping to increase awareness about clinical trials within the community of interested patients.

MARKETING AUTHORISATION

Patients may play an increasing role in regulatory processes, which in Europe may lead to the granting of a marketing authorisation, input into pharmacovigilance, or provide real world evidence that may further inform the regulation of medicines. Regulators require access to a pool of patients who act as experts in their disease area, to inform the regulatory process. In regulatory terms, patients should provide input into medicines development by participating in scientific advice/protocol assistance procedures for specific medicines. With regard to the benefit/risk evaluation of medicines both pre- and post-authorisation, patients can take part in expert meetings convened by committees, contributing to written consultations on specific medicines from scientific committees/working parties. Patient views are also important for communications on medicines, providing valuable input into the review of information on medicines, including package leaflets, European Public Assessment Report (EPAR) summaries, safety communications (Q&As) and other Agency documents for the public. It is essential the regulatory process to be transparent for patients, as this provides trust in the regulatory process and the medicines that emerge from it.



THE EUROPEAN MEDICINES AGENCY (EMA) AND PATIENTS HAVE BEEN ACTIVELY INTERACTING SINCE THE CREATION OF THE AGENCY IN 1995. THIS COOPERATION WAS EXTENDED TO INCLUDE CONSUMER GROUPS WITH AN INTEREST IN MEDICINES. BOTH OF THESE STAKEHOLDER GROUPS BRING A 'REAL-LIFE' EXPERIENCE AS WELL AS SPECIFIC KNOWLEDGE AND EXPERTISE TO SCIENTIFIC DISCUSSIONS ON MEDICINES AND ON THE IMPACT OF REGULATORY DECISIONS. COLLABORATING WITH THESE GROUPS SUPPORTS TRANSPARENCY AND IMPROVES REGULATORY PROCESSES.

EUROPEAN MEDICINES AGENCY⁶

⁶ http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000317.jsp&

VALUE ASSESSMENT

Patient involvement in Health Technology Assessment (HTA) processes is evolving in Europe, but there is a role for patients to play in defining the value of medicines. Working independently and in collaboration with HTA bodies, they may contribute to the HTA process by helping to prioritise patient-relevant HTA topics, identifying patient-relevant health outcomes and other impacts (economic, social, etc.) for assessment, providing relevant evidence as input to assessment, and review and comment draft HTA reports and recommendations. In order to provide this input, patients should be able to serve as members of HTA boards, committees, and workgroups. They should also contribute to the design and preparation of patient-friendly HTA report summaries and the dissemination of HTA findings to policymakers, patient groups, and other interested groups. Patient Organisations are also increasingly building on HTA recommendations to inform their action and support appropriate access to therapies, in line with evidence-based recommendations issued by HTA agencies.



PATIENTS CAN PROVIDE INFORMATION AND INSIGHT, ABOUT THE IMPACT OF THEIR CONDITION AND TREATMENTS ON THEIR DAILY LIVES THAT IS NOT AVAILABLE ELSEWHERE. PATIENTS ARE IN A UNIQUE POSITION TO DESCRIBE THE OUTCOMES THAT MATTER TO THEM, TO CHALLENGE PRESUMPTIONS ABOUT THEIR HEALTH ASPIRATIONS AND TO INFORM HTA PROCESSES ABOUT THE POTENTIAL POSITIVE OR NEGATIVE EFFECTS OF NEW AND EXISTING TECHNOLOGIES - ON THEIR HEALTH AND ON THEIR ABILITY TO LIVE AND WORK.

EUROPEAN PATIENTS ACADEMY INITIATIVE⁷

MEDICINES PRESCRIBED TO PATIENTS

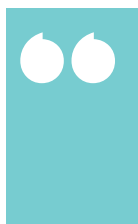
Patients and Patient organizations can share with all stakeholders' real world challenges and potential solutions to appropriate medicine use. There are numerous examples of patient led data that can generate evidence based and patient focused/patient friendly guidance on the appropriate use of medicines to prevent abuse, reduce medication errors and wastage, and foster patient education. Engagement between patients and healthcare professionals can lead to collaborative treatment decisions, tailored to suit to the patient. Patients are also instrumental in working with medicines manufacturers to improve medicines and their use by contributing their experiences and understanding of their own condition.

PATIENT ORGANISATIONS AND THE UTILISATION OF REAL WORLD DATA

The potential of health informatics to help in the delivery of better health outcomes that are relevant to patients is well acknowledged. Moreover, the collection, collation and utilisation of Real World Data/Big Data is set to become instrumental in decisions that affect patients' access to medicines. Not only can the use of RWD help to inform clinical trial design, making studies more appropriate, comfortable and acceptable to patients, it can also be used to inform predictive modeling, which could help to identify new and more successful candidate molecules that could be tailored to suit patient needs. RWD will also play a vital role in creating the next generation of medicines and shaping future research. An increased focus on data would further improve pharmacovigilance procedures, making medicines safer for patient use. In terms of the vital data protection required to ensure patient privacy

⁷ EUPATI: https://www.eupati.eu/health-technology-assessment/guidance-for-patient-involvement-in-hta/#Overarching_principles_for_patient_involvement_throughout_the_medicines_research_and_development_process

and trust, the right balance needs to be reached between ensuring confidentiality of data while allowing their availability and sharing for public health, healthcare and research purposes.



PATIENT DATA IS HUGELY VALUABLE FOR RESEARCH. BUT THE VALUE OF THAT DATA CAN ONLY BE UNLOCKED IF CONCERNS ABOUT PATIENT PRIVACY ARE TAKEN SERIOUSLY.

WELLCOME TRUST⁸

SUPPORTING THE CREATION OF MORE PATIENT OUTCOMES-FOCUSED HEALTHCARE SYSTEMS

As healthcare systems across Europe look at the long-term sustainability of healthcare delivery through outcomes-focused healthcare, patients and Patient Organisations have a key role in helping to shape, develop and define the outcomes that make the most difference to patients.

Outcomes-focused healthcare is predicated on the capture and analysis of healthcare (outcomes) data. That means using patient's data to shape the future of healthcare. Understanding perspectives on the confidentiality, stewardship and use of healthcare data is critical to healthcare systems realising their potential.



OUTCOMES ARE THE RESULTS OF TREATMENT THAT PATIENTS CARE ABOUT MOST.

OUTCOMES ARE NOT "OUTPUTS"; THEY ARE NOT LAB RESULTS; THEY ARE NOT TECHNICAL DETAILS. THEY'RE REAL-WORLD RESULTS, LIKE PHYSICAL FUNCTIONING OR LEVEL OF PAIN. UNFORTUNATELY, TODAY, IN HEALTHCARE SYSTEMS AROUND THE WORLD, EVALUATION EFFORTS TAKE INTO ACCOUNT A NUMBER OF CLINICAL INDICATORS, STRUCTURAL METRICS, AND EVEN REPUTATION – BUT THEY TEND TO IGNORE OUTCOMES.

INTERNATIONAL CONSORTIUM FOR OUTCOMES MEASUREMENT, 2016

⁸ <https://wellcome.ac.uk/what-we-do/our-work/our-policy-work-using-patient-data-research>

6. POTENTIAL HURDLES AND PROPOSED SOLUTIONS

The list of potential hurdles below does not constitute an exhaustive list, but should be read as examples of challenges to be addressed.

POTENTIAL HURDLE: Irrespective of the strong rationale for engagement, any relationship between Patient Organisations and pharmaceutical industry can be perceived as commercially motivated.

PROPOSED SOLUTIONS



All collaboration should have a clearly identified patient benefit and legitimate need.



The aims, objectives and desired outcomes of a project must be transparent and proactively, publicly communicated.



Good governance in reporting, adherence to laws, codes of practice and guidelines.



Many organisations and pharmaceutical companies publicly display their codes of conduct and governance that dictate their relationship with each other and in the case of Patients Organisations, articulate decision-making processes independent of industry.

POTENTIAL HURDLE: Patient organizations are invariably challenged to fund their activities and their work. Many organizations rely upon the pharmaceutical industry to support their work. Despite strict adherence to the Code of Conduct that dictates the relationship, this may lead some to assume there is undue or inappropriate influence of the industry on patient organizations and their decision-making.

PROPOSED SOLUTIONS



Transparency of financial relationships from both industry and the Patient Organisations. Industry disclosure of transfers of value to patients is a requirement of the EFPIA Code of Practice on relationships between the pharmaceutical industry and Patient Organisations.



Diversity of funding sources is encouraged to support independence. The EFPIA Code stipulates that companies cannot require to be sole funder of projects and organisations.



Good governance in reporting, adherence to guidelines and Codes of Practice.



Many organisations publicly display their codes of conduct and governance that dictate their relationship with the industry and articulate decision-making processes independent of industry.

POTENTIAL HURDLE: Pharmaceutical companies are often global organisations with complex structures. Identifying the right contact point and how to manage relationships can be challenging for Patient Organisations.

PROPOSED SOLUTIONS



Company online resources to sign-post patient groups to the right contact points



The [EFPIA PO Code](#) provides a framework in terms of how to approach this relationship.

POTENTIAL HURDLES: Meaningful engagement in HTA and regulatory processes requires resources, expertise and significant staff-time. This is particularly challenging for smaller Patient Organisations.

PROPOSED SOLUTIONS



Capacity building within the Patient Organisations through initiatives like EUPATI.



A series of measures by HTA and regulatory bodies would lead to the long-term objective of patient participation and uptake as highlighted by patients in the recent European Commission Consultation Report on Strengthening of the EU cooperation on HTA.



Creation and resourcing of patient engagement processes: processes well established at EMA should serve as a model for HTAs.

POTENTIAL HURDLE: Increasingly Patient Organisations engage with companies from a number of sectors such as innovative pharmaceutical companies, generics manufactures, medical devices, diagnostics and healthcare data companies. In practice this means managing multiple codes of practice and terms of engagement, particularly where companies from different sectors are involved in one collaborative project.

PROPOSED SOLUTIONS



Long-term objective of greater alignment of codes of practice across sectors



Capacity building within the Patient Organisations to understand content and implementation of relevant laws, industry codes of practice.



Communication within Patient Organisations and pharmaceutical companies to ensure common knowledge and understanding of the principles contained in this paper.

POTENTIAL HURDLE: Ensure Patient Organisations are included in the discussions conducted by regulatory bodies.

PROPOSED SOLUTION



Implement the same process as the one for Healthcare Professionals to prevent conflict of interest and independence when involve in public authorities discussions/processes.

7. APPENDICES

APPENDIX 1:

Definition of terms

[EUPATI glossary](#)

APPENDIX 2:

Legal requirements, relevant codes and best practice guidelines

[EUPATI diagram on Patient involvement in medicines R&D](#)

[The Alma Ata Declaration \(WHO\)](#), see article IV on the moral imperative to involve patients in the delivery and planning of healthcare: “The people have the right and duty to participate individually and collectively in the planning and implementation of their health care.”

EPF’s legitimacy criteria for membership explained [here](#).

[EPF’s Framework for cooperation](#). The EUPATI Guidance for patient involvement in industry-led R&D is still under consultation but [here](#) is where you can find it

EUPATI Guidance/Frameworks:

- [Framework for patient involvement in regulatory processes](#)
- Framework for patient involvement in HTA
- Framework for patient involvement in industry-led medicines R&D
- Framework for patient involvement in ethics committees

[The EFPIA Code](#)

[Efpia Code of Practice on the Relationship between the Pharmaceutical industry and Patient Organisations](#).

Principles of interactions with Patient Organisations are outlined in the EFPIA PO Code of Practice, and that this document doesn’t replace them. Companies cannot engage with Patient Organisations beyond the scope of the Patient Organisation Code and cannot impose ways of working on Patient Organisation partners.

[Industry/Patient Organisation MoU](#)

Further references

[EPF Toolkit on Fundraising for patient organisations](#)

EPF Guidelines on transparency for patient organisations (currently under development)

[EFPIA Health Collaboration Guide](#)

8. ABOUT THE EFPIA PATIENT THINK TANK

The EFPIA Patient Think Tank provides a forum for an open exchange of ideas, information and perspectives between Patient Organisations and industry on topical issues impacting on patients. Our aim is not to create common positions, but to ensure that the patient voice is heard in the development of EFPIA policy and practice and give industry members the opportunity to discuss aspects of medicines research and development with the Patient Organisations' community. No subject is off the table and as a group we have discussed topics such as outcomes focused healthcare, medicines pricing, patient engagement in HTA, healthcare data and collaboration. The Think Tank is keen to take dialogue and debate beyond the membership of the group, through the annual Health Collaboration Summit. The event brings together Patient Organisations, policy makers and industry leaders from across Europe, to discuss key healthcare topics. The emphasis is on giving a voice to different perspectives from a board range of stakeholders and ensuring an interactive debate. As part of the Summit the Think Tank also hosts the Health Collaboration Awards for collaborative projects that have delivered patient benefit. The aim of the awards is to share best practice and provide food for thought and inspiration to stakeholders considering developing multi-stakeholder projects that benefit patients. As European Healthcare continues to face significant challenges it is critical that there is open dialogue between stakeholders. The Think Tank plays an important role, providing a forum to share information, support best practice and exchange perspectives.

