abpi
Bringing medicines to *life*

Patient involvement in the development of medicines

The pharmaceutical industry is working in different ways with patients and healthcare professionals

- Industry is working in different ways to engage with healthcare professionals, patients and patient groups as the science changes.
- Patient groups are ‘at the table’ earlier in discussions, becoming more involved in clinical trials and transparency is increasing. Increasingly patients and patient groups are actively engaging in the process of how medicines are developed to provide valuable insight.[1]
- More and different groups are taking responsibility for putting together the evidence and undertaking the assessment of medicines.
- As the Accelerated Access Review recognises ‘Patients should be involved in horizon scanning and prioritisation, and this involvement should continue along the whole innovation pathway. The NHS should use a common set of principles describing what good partnership with patients and the public looks like along the whole innovation pathway.[2]

1. https://www.eupati.eu/
2. The Accelerated Access Review: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/564145/AAR_final_A.pdf

Patients First Conference – AMRC and ABPI

Patients and representatives from across the medical research sector came together in November 2016 at the inaugural Patients First Conference, hosted jointly by the Association of Medical Research Charities (AMRC) and the Association of the British Pharmaceutical Industry (ABPI), to explore how medical research can deliver better outcomes for patients.

The event brought together over 300 delegates – including patients, charities, industry, research bodies, funders and government – who, with a shared recognition that patients play a vital role in medical research, explored how they can collaborate to put patients first, involving them in research and development through to care and access to treatment, to ultimately deliver them the best outcomes.[1]

1. http://www.abpi.org.uk/media-centre/newsreleases/2016/Pages/Patients-health-and-research-experts-unite-to-put-patients-first-in-medical-research.aspx

Patient involvement in medicine development - from theory to reality[1]

What is EUPATI?

eupati.eu/what-is-eupati/

The European Patients' Academy (EUPATI) is a pan-European Innovative Medicines Initiative (http://www.imi.europa.eu/) project of 33 organizations, led by the European Patients' Forum, with partners from patient organizations (the European Genetic Alliance, the European AIDS Treatment Group, and EURORDIS), universities and not-for-profit organisations, along with a number of pharmaceutical companies.

We focus on education and training to increase the capacity and capability of patients to understand and contribute to medicines research and development and also improve the availability of objective, reliable, patient-friendly information for the public.

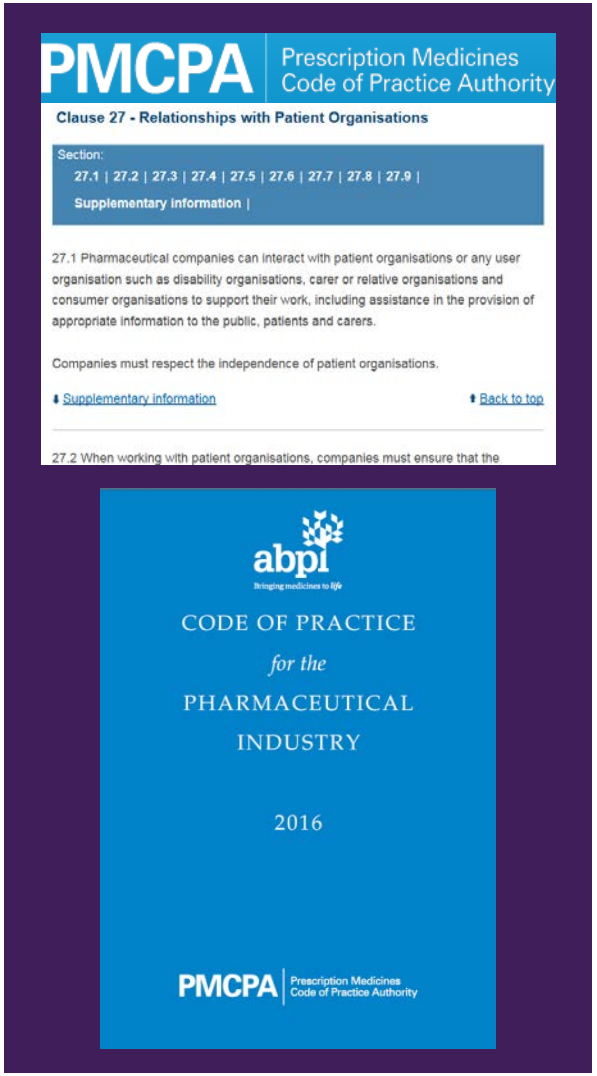
EUPATI 2014 Workshop: Reaching a Public Audience on Medicines Development

Alongside its patient expert training programme, the patient-led European Patients' Academy (EUPATI) has set out to inform the European patient community on how new medical treatments are developed. More than 150 representatives from patient organisations, academia, industry and regulatory affairs met in Warsaw on 2 April 2014 to plan the next stage of an ambitious European project aimed at increasing the knowledge of the lay public about the development process of new medicines. The input received at the workshop will help shape the project's strategy. Here you find the press release, our Twitter wall, as well as presentations and movies shown during the EUPATI 2014 Workshop.

1. https://www.eupati.eu/

We are committed to transparency, setting and following high standards for how we behave

- All ABPI members are required to adhere to the ABPI Code of Practice for the Pharmaceutical Industry and has strong support from the MHRA who have agreed to abide by the ABPI Code of Practice.
- It also applies to non-members who have agreed to abide by the ABPI Code of Practice
- Administered by the Prescription Medicines Code of Practice Authority (PMCPA) , a self-regulatory body operates the code at arm's length from the ABPI.
- The PMCPA is a not-for-profit body which was established by the ABPI on 1 January 1993.
- The code includes specific requirements on relationships with patient organisations under Clause 27.
- The ABPI Medical Representatives Exam is taken by representatives who call upon healthcare professionals. An appropriate examination must be taken by all representatives working for companies who have agreed to abide by the ABPI Code within one year of employment and passed within two years.



PMCPA. http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf

We launched the ABPI Patient Organisation Forum (POF) in 2014[1]

Brings together representatives of the pharmaceutical industry and patient and charity groups in an open forum

Aims

- To identify areas of mutual interest
- To promote understanding
- To develop joint working on policy and practice, where appropriate

By facilitating ongoing dialogue, open discussions and information sharing on issues of common interest, including healthcare policy

Strong governance and co-operation

- Supported by **steering group** of patient groups and company representatives
- All **meetings co-chaired** by a member company representative and patient group representative
- **Transparency:** Summaries of meetings and attendance published on the ABPI website [1]

1. ABPI. Patient Organisation Forum. www.abpi.org.uk/our-work/patient-organisation-forum

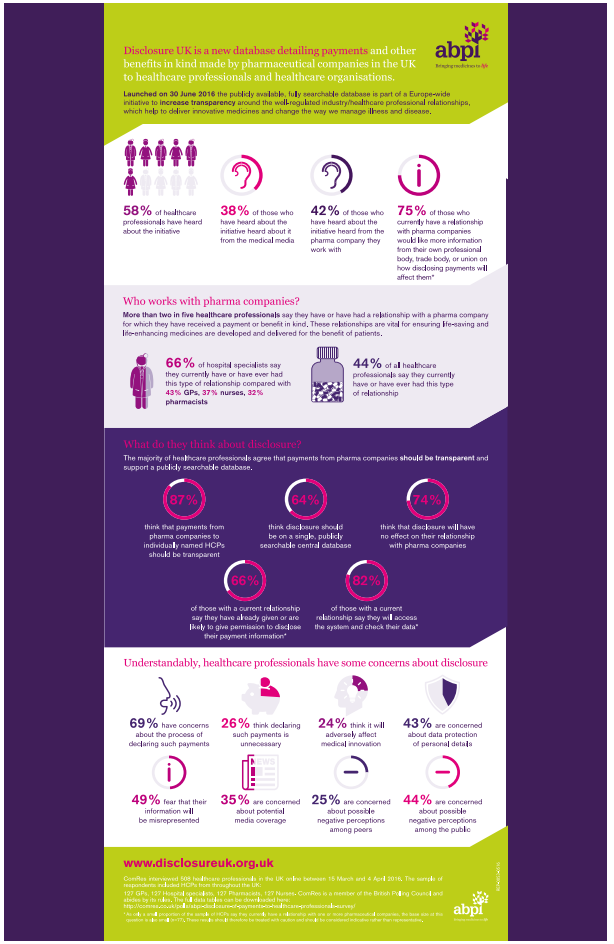
Together we produced the ‘Patient Guide’

- ABPI and National Voices jointly produced a guide[1] to collaboration between pharmaceutical companies and charities. The guide aims to promote transparency and accountability in collaborative working and to serve as a practical 'how to' guide for all parties. This has also been part of the ABPI Code of Practice since 2006.
- It has been led by a steering group, chaired by Harry Cayton CBE, Chief Executive of the Professional Standards Authority.
- The project included two workshops, a survey and a series of interviews to consult stakeholders and help shape the guide.
- The guide was published in July 2015.
- Together the pharmaceutical industry is actively engaging in activities that support patients

1. National Voices and ABPI ‘Working together, delivering for patients: A guide to collaboration between charities and pharmaceutical companies in the UK ‘ http://www.abpi.org.uk/our-work/library/Documents/ABPI_NV_Guide_FINAL.pdf

Transparency in partnership with healthcare professionals and healthcare organisations

- In June 2016, pharmaceutical companies started to publish details of certain payments made to individual, named, healthcare professionals.
- This information is published on a central UK database, fully accessible to members of the public. Patients can search for the name of their doctor or other healthcare professionals, health care organisations, to see what payments an individual may have received, from which company, for what type of activity.
- The new requirements are part of an industry-wide initiative in 33 European countries, bringing greater transparency to the interactions between healthcare professionals and pharmaceutical companies.
- The new initiative builds on existing requirements in the ABPI Code of Practice which has, since 2012, seen companies publish the total, aggregate amount they pay to healthcare professionals.
- Click here[1] to search the database.



1. ABPI: Disclosure UK Database: http://www.abpi.org.uk/our-work/disclosure/Pages/DocumentLibrary.aspx

Transparency in clinical trials

- The ABPI is a strong advocate for transparency in clinical trial information. It is a requirement of the ABPI Code of Practice and has been for several years. This is included in the EFPIA Code of Practice.[1]
- Companies are required to publish all clinical trial results within one year of marketing authorisation and publically register new clinical trials within 21 days of the first patient being enrolled.
- In February 2013 the ABPI launched a disclosure toolkit for companies to help them meet the requirements for clinical trial transparency under the ABPI Code of Practice.[2]
- This toolkit provides good practice guidelines, disclosure checklists and a template standard operating procedure for pharmaceutical companies.
- These materials are updated regularly in line with changes to international regulatory requirements.
- Companies have also signed up to the EFPIA-PhRMA principles[3] for responsible clinical trial data sharing to enhance research and data sharing efforts by making additional information available to the public, patients who participate in clinical trials and qualified researchers.[4] Ultimately this move aims to benefit patients and foster scientific discovery.

ClinicalStudy DataRequest.com

Advancing science and improving care, Astellas, Bayer, Boehringer Ingelheim, Daiichi Sankyo, Eisai, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB and ViiV Healthcare all sponsor ClinicalStudyDataRequest.com[5] which allows researchers to request access to anonymised patient-level data from clinical studies to conduct further research.

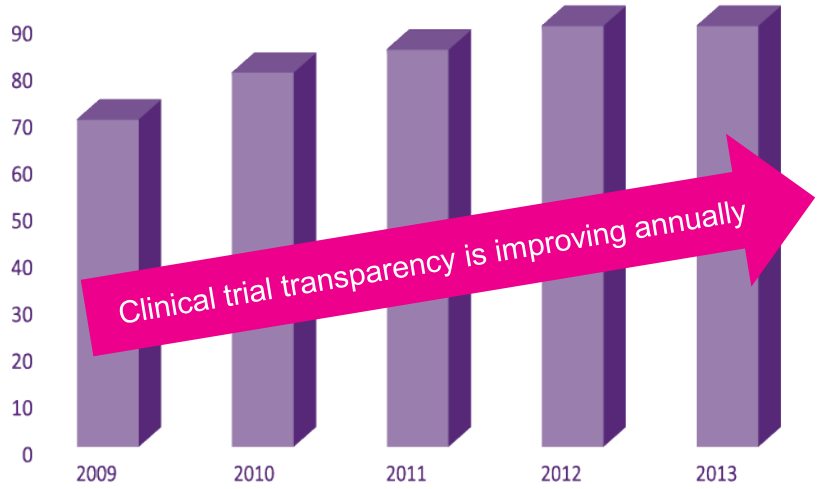
GSK was the first company to sign up to All Trials in 2013, which calls for the registration of clinical trials and the disclosure of trial results and clinical study reports[5] (CSRs). CSRs are the formal study reports that we prepare, to provide more detail on the design, methods and results of our clinical trials.

1. EFPIA Code. http://transparency.efpia.eu/the-efpia-code-2
2. ABPI Clinical Trial Disclosure Kit. http://www.abpi.org.uk/our-work/library/guidelines/Pages/ABPI-disclosure-toolkit.aspx
3. EFPIA.Joint EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing Become Effective. http://efpia.eu/mediaroom/132/43/Joint-EFPIA-PhRMA-Principles-for-Responsible-Clinical-Trial-Data-Sharing-Become-Effective
4. EUPATI. Clinical development and trials. https://www.eupati.eu/category/clinical-development-and-trials/
5. Clinical Study Data Request: https://clinicalstudydatarequest.com/

Improvements in clinical trial transparency

- Research shows industry commitment to greater transparency of company-sponsored current and future clinical trials is making a difference.
- The disclosure rates of results for clinical trials for medicines licensed in Europe between 2009-2013 has seen a steady improvement from 71% in 2009[1] to 90% in 2013[2].
- Companies are developing innovative processes and solutions to share clinical trial data with researchers to enable greater advances in scientific discovery and patient care.[3]
- The EFPIA responsible transparency platform provides a gateway to many of these solutions.

> We are seeing a sustained trend towards improved disclosure of industry-sponsored trials associated with new medicines.[4]
>
> Dr Bryan Deane



1. Rawal B & Deane BR. 2014. read Clinical trial transparency: an assessment of the disclosure of results of company-sponsored trials associated with new medicines approved recently in Europe. http://www.tandfonline.com/doi/abs/10.1185/03007995.2015.1047749
2. Deane BR & Sivarajah J. Nov 2016. Clinical trial transparency update: an assessment of the disclosure of results of company –sponsored trials associated with new medicines approved in Europe in 2013 https://www.ncbi.nlm.nih.gov/pubmed/27869482
3. EFPIA Clinical Trial Data Portal Gateway
4. ABPI Press Release - http://www.abpi.org.uk/media-centre/newsreleases/2016/Pages/90-per-cent-of-pharmaceutical-industry-led-clinical-trials-now-published,-says-new-study.aspx

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