

Supporting patient and public involvement in industry-led research: guidance for charities

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If you only read one section of this guidance, make it this one.

This guidance has been developed by the Charities Research Involvement Group in collaboration with the Health Research Charities Ireland. It aims to help charities in the UK and the Republic of Ireland to promote and support patient and public involvement (PPI) in industry-led research. This field is complex so this guidance is long. If you just want a taster, here are some top tips:

Top tips from the charities that shared case studies

Work with PPI contributors to develop a governance structure and policy on working with industry as early as possible – including your organisation’s stance on whether to accept payment to support involvement. This will help you decide who to work with.

Get a sense of the motivations of one another right at the beginning. Tokenistic involvement is detrimental for everyone.

There can be nervousness around a charity and an industry partner working together. Some challenges are easily avoided by being open and honest about the collaboration and not compromising on the principles of involvement.

Start the contractual process between organisations as early as possible and involve legal teams from the outset. This will avoid things being lost in translation.

Identify a key contact to work with. Recognise that it will take patience, sufficient resource, a lot of time and really good communication to work together successfully.

Explore whether people can be involved at multiple stages of the project, rather than at just one point.

Make sure that you clearly communicate the aims of the research and the PPI to those who are involved.

Accept that you're not going to deliver something perfect – but know that it will be valuable and informative for the future.

Top tips from PPI contributors

Be clear about the charity position and motivations from the start. If you are going to work with pharmaceutical companies, don't be apologetic about it. Accept that some PPI contributors will want to work with the pharmaceutical industry and others won't. That's okay.

Encourage collaboration early in a study rather than when there is already a protocol in place. This can lead to unexpected insights in parts of the study where patients' experience may not have been considered to be useful.

Advance notice is crucial for patients who may have a great deal of experience to share but also have medical conditions to manage on top of all the other aspects of their lives.

The patient agreement/contract should be written in a balanced tone.

Paperwork: Patients are unlikely to have the technical support that charities and pharmaceutical companies have. Don't assume everyone has a printer or scanner. They don't.

Encourage industry to offer compensation to those who're involved. This can take many forms.

Be precise with your ask to those you're involving. If you're not clear, the discussions and comments won't be focused.

Communication is key. Provide information leading up to the activity, a summary of what happened and how it will be used, and what's happening next. Updates explaining why nothing appears to be happening are also really valuable.

Foreword

Recently there seems to have been a growing interest in involvement in this type of research – not just from an increasing number of charities, also but from more and more pharmaceutical companies.

I've been wondering for years about how we (charities, patients, carers and others who believe that involvement can improve the quality of research) can work effectively with the pharmaceutical industry to ensure that the research it does reflects the priorities and needs of people who will end up using its products. A few pharmaceutical companies and patient groups have been doing this for a while – but the learning from this hasn't always been easily available.

So, for a long time working with industry felt too hard. But recently there seems to have been a growing interest in involvement in this type of research – not just from an increasing number of charities, but also from more and more pharmaceutical companies. How can we make this type of involvement meaningful for everyone, when charities and industry come from very different starting points, and work within very different frameworks?

Colleagues from the Charities Research Involvement Group – a group of charities that are committed to involvement in research and that I am proud to facilitate – have come together to develop guidance to address this 'how to?' gap. This guidance has drawn on the experience of a few charities that have been doing this type of work, and the questions of other charities that want to. Thanks to Claire Nolan, who did the writing on our behalf, and to the PPI contributors and colleagues from the pharmaceutical industry who helped us hugely.

The process of putting together this guidance has helped us to understand more about supporting involvement in industry-led research. I hope it helps those who read it to develop meaningful and productive relationships more quickly and effectively.

Bec Hanley

Facilitator, Charities Research Involvement Group

Together we will be able to ensure that patient, public and carer involvement in research can take place, does take place, and does make a difference.

We're incredibly grateful to those tens of thousands of patients who advise, participate in and support clinical research every year to help us develop medicines of the future.

However, in order to make the medicines of the future meaningful for patients, we need to partner with patients, the public and carers in how we design our clinical research. These perspectives are a key part of making sure that the trials that patients are taking part in will give us answers about whether medicines work or not.

At ABPI, we've been working with the Charities Research Involvement Group to work out how we practically make this happen. How can industry and research charities and patients work together in clinical research?

In June 2019, ABPI published our Sourcebook, bringing together guidance for the industry. I'm delighted to see this guidance for charities which complements the ABPI Sourcebook. Together we will be able to ensure that patient, public and carer involvement in research can take place, does take place, and does make a difference.

Sheuli Porkess, BM BCh MA FFPM MRCP
Executive Director, Research, Medical and Innovation
The Association of the British Pharmaceutical Industry

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1. Introduction

This guidance has been developed by the Charities Research Involvement Group – a group of UK charities with a commitment to actively involving patients and carers in the research we fund and support, and to sharing what we learn about this with each other and more widely.

The guidance aims to help charities in the UK and the Republic of Ireland to promote and support PPI in industry-led research. It's not about how to work with the pharmaceutical industry in general – there's lots of excellent information available on this already. It's also not about how to 'do' PPI in research in general – again there is plenty of information available on this. This guidance focuses on what's different about working with the pharmaceutical industry on PPI in research.

In this guidance we have used the following terms:

- **Patient and public involvement (PPI)** means the active involvement of patients, carers, family members and members of the public in the research process ([see www.invo.org.uk/frequently-asked-questions/](http://www.invo.org.uk/frequently-asked-questions/) for more information on this definition).
- **PPI contributors** are the patients, carers and other people affected by a condition who get actively involved in research.
- **Industry (or pharmaceutical industry)** refers to pharmaceutical companies and biotechnology (biotech) companies.

We recognise that these terms are not universally accepted and that they may mean different things to different organisations – for example when thinking about PPI, industry may talk about 'patient centricity' or 'patient engagement'. In many charities, PPI contributors may be referred to as 'people affected by...' (and the name of the condition the charity works in).

Please note that companies developing and selling digital and medical devices are not specifically included in this guidance, but you may find this guidance useful when engaging with such companies. Be aware that the regulations and approval processes governing and driving these companies may be different.

2. Laying the foundations

Whether you are approached by a company or you would like to approach a company, laying the right foundations to understand regulations, opportunities and risks is essential. This will also ensure that any interactions are based on an agreed purpose, that each organisation remains independent, and that the interaction is transparent and based on integrity. Laying these foundations is a good investment for your charity's future, is more likely to benefit your supporters and will enable you to work with companies with confidence.

What is your organisation's policy on working with industry?

Before you consider working with industry, find out if you have an up-to-date policy on working with industry in place. This should set out principles, rules and guidelines adopted by your organisation. It will also help you to answer any potential questions that arise from your organisation's work with industry.

Views from some PPI contributors about charities working with industry

"For me it is really important to know that Parkinson's UK works closely with the pharmaceutical industry. Knowing that my voice can be heard, and listened to, through the PPI programme means that what is important to me as a person with Parkinson's becomes important to those companies as well."

Mark Hoar, PPI contributor, Parkinson's UK

"Charities and industry have different perspectives on research. Charities are working in the interests of the patients and industry, whilst helping many patients, is profit-making. These differences need to be acknowledged in the first instance to allow transparency in any liaison."

Some questions to consider include:

- *What is the company's ultimate goal; what is driving it to do PPI?*
- *Will it commit to sharing outcomes with patients?*
- *Will it genuinely take into account the views of patients?"*

*“Be clear about the charity position and motivations from the start.
If you are going to work with pharma, don’t be apologetic about it.”*

Combined quotes from various PPI contributors

If you do not have an up-to-date policy in place, you should consider developing one. To do this you will need to:

- Gain support from your trustees and senior leadership team.
- Understand any relevant guidelines or legal requirements for working with industry partners.
- Involve members of the community you support e.g. patients and carers, as well as supporters of the charity.

Any interaction or collaboration with industry to support PPI could develop into a larger partnership with other areas of the charity, so involve all individuals or departments that could potentially work with industry (these could be teams responsible for education programmes, teams supporting management of the condition, research teams or fundraising teams).

Examples of charities’ organisational policies on working with pharmaceutical companies include:

MS Society
Bloodwise
British Heart Foundation
Prostate Cancer UK

An excellent resource that will help you in developing your policy is “Working together, delivering for patients: A guide to collaboration between charities and pharmaceutical companies in the UK”. This has been developed by National Voices and the Association of British Pharmaceutical Industry (ABPI) and sets out principles for collaboration. It also has a useful list of other resources that may be helpful when developing policy (i.e. Charity Commission guides).

In Ireland, Health Research Charities Ireland (HRCI) has developed a template Code of Practice to guide engagement between charities and industry. This code takes into consideration the governance requirements of industry but has been developed from the patient organisation perspective. It can provide a starting point for what

patient organisations need to consider when dealing with industry and can be adapted according to the situation and needs of individual organisations.

Some charities have decided that it isn't appropriate to develop a distinct policy for working with industry. Instead they have developed a policy which covers both academic and industry-led partnerships. Others have developed a more general 'partnerships policy'; which covers if, when, and how they work in partnership with stakeholders.

Whether you have an industry specific policy or a more generic one, you should have a transparent process in place to decide which companies you will work with. This should include information about how you will appraise the potential benefits and risks, and the hierarchy of escalation for approval from the PPI lead, through management and to the Trustees, where appropriate. See Autistica's policy for a good example of this - www.autistica.org.uk

Do you understand your supporters' attitudes to working with the pharmaceutical industry?

Many people with health conditions appreciate that the pharmaceutical industry is essential for ensuring new and better medicines for people who need them most. But there can still be an issue of trust when it comes to 'Big Pharma'. People have many valid questions around the cost of treatments, industry motives, perceptions around profits and salaries for executives.

Resources permitting, it is valuable to do some work to understand what your supporters think about the pharmaceutical industry and, importantly, what they think about your organisation working with industry. Understand the reasons why people might want you to work with industry and why they don't. For example, drug prices are often a concern for patients and might be a reason they do not want your organisation to work with the pharmaceutical industry. Pricing is a complex area and is dictated by a number of factors, including the cost of research and development which can include the failure of many potential new drugs. Whilst you may not have the answer to every concern, be prepared to do some carefully considered communication. You may find that listening and responding could help change people's perspectives. Those people whose minds you can't change may be in the minority. You should be respectful and willing to engage with them about

their concerns and demonstrate that you have good community support for this way of working.

Which area of a company will you work with?

Companies within the pharmaceutical industry are often multinational organisations with both global and local (national) departments which can include Research & Development (R&D), Medical Affairs, Communications, Public Affairs, Market Access, Marketing and Legal & Compliance. It is good to be clear about which area or department of a company you will support with PPI. For example, would your organisation prefer to support only R&D activities, or would you be happy to work with a company on a patient education and support programme? The nature of PPI in research might suggest R&D only. However, potential industry partners may believe that all of these areas are important components of developing a new treatment and ensuring that a treatment receives regulatory and Health Technology Assessment (HTA, e.g. NICE in the UK) approval. This is something you should decide with both colleagues and supporters, in line with your policy.

Should you accept payments from industry?

One of the key decisions you will need to make is whether or not to accept payment from industry for your support. There is no one right or wrong answer to this. It will depend on your policy, how you currently support academic researchers, and what the resource capabilities are within your team. Charities have much to gain from entering into partnerships with companies. But whilst a partnership can raise a charity's income and profile, it also comes with risks, including potential scrutiny from the media and/or supporters. Charities should take appropriate steps (such as those outlined in the previously mentioned National Voices/ABPI guidance) to address these risks before deciding to accept payment. If you are accepting payment, it is important to be clear and have an agreement from the very start about what you are being paid for.

Things to consider when thinking about payment

Accepting payment from industry could help your charity significantly in terms of income, allowing you to focus on areas you would otherwise not and enabling funds to be invested in extra resource or developing and delivering other projects of benefit to people affected by health conditions.

Taking payment can also come with operational challenges (e.g. conflicts of interest in other areas of work, such as policy making) and reputational risk (e.g. supporters' views on working with industry or if any incidents happened involving the company). In addition, you may have less control over the direction of the project or if you experience difficulties in delivering the project (potentially due to time or resource) you may face pressure to deliver the agreed work.

If your organisation decides against accepting payment, there may be reputational benefits, including being seen by your supporters and potentially others as independent. If your organisation is dedicating time and resource without payment from the pharmaceutical industry, there may also be reputational benefits in demonstrating that your organisation is willing to invest in ensuring that people affected by health conditions are at the centre of research and medicines development.

This work, however, can be time consuming and resource intensive and you may have to limit other work as a result. Therefore, you may face criticism from your supporters, as people's donations could be seen as benefitting a 'for-profit' industry. Also, bear in mind that regardless of cost recovery, fee for service or collaboration involving no payment, relationships with industry should involve some type of agreement or contract which will inevitably take up resource and time.

In conclusion, each organisation must consider the benefits, challenges, organisational needs and supporter attitudes to decide its own position on funding.

Collaborations between charities and industry, whether they involve payments or not, should demonstrate a clear purpose that benefits patients and ways of working that are based on the principles of integrity, independence, accountability, and transparency.

UK and Irish Codes of Practice for the pharmaceutical industry

In the UK, the pharmaceutical industry must abide by the ABPI Code of Practice. The aim of the Code is to ensure that the promotion of medicines to health professionals and other relevant decision makers and other activities are carried out within a robust framework to support high-quality patient care. This Code of Practice concerns the pharmaceutical industry only. It does not cover medical device or technology companies.

Topics covered in the code include regulations on the information and promotion of prescription-only medicines and working with patients and patient organisations (specifically Clause 27 contains detailed provisions for industry on relationships with patient organisations). These regulations are important in protecting both patients, patient organisations and companies when working together.

To complement the ABPI Code of Practice, the ABPI has produced a Sourcebook to support pharmaceutical companies to work successfully with patients and patient organisations. This useful document can help increase your understanding of the ABPI Code of Practice and the opportunities and restrictions of working with industry to support PPI.

It is also worth mentioning that the ABPI is an approachable organisation and encourages people to contact it for help or advice if needed on **+44 (0) 20 7930 3477**.

The Irish Pharmaceutical Healthcare Association (IPHA) has a code of practice for its members which provides a guideline for companies on working with patient organisations - see www.ipha.ie/About-Us/Our-Role/Codes-of-Practice

3. First steps

Where do you start in developing a relationship with industry?

There are a number of ways you could begin developing this area of work. Being proactive is key, because many companies still have a long way to go before PPI becomes the norm. Often, they are not sure where to start, so approaching them could be the beginning of some really successful work.

The first thing to check is whether your organisation already has an existing relationship with any companies, present or past. Was the relationship a successful one? Does the company share your goals and work in a transparent way? If your organisation does not have a relationship with any companies, perhaps some of the healthcare professionals you work with have views on particular companies they feel are working with integrity?

Here are some of the ways other charities have developed relationships with industry:

Hold a scoping meeting and invite patients and industry representatives along

If you do not already have strong relationships with industry and want to understand how you can best support companies with PPI in their research, holding a scoping session, discussion meeting or workshop can be useful. Depending on your needs, the meeting could involve representatives from one or more companies, members of your team, patients and carers. When planning such a meeting think about what you would like to achieve. Is it a meeting to scope out initial ideas or do you have a programme of work in mind that you would like to discuss and get feedback on? Are there particular companies you would like to invite i.e. companies with an interest in a specific health condition, companies running lots of trials in the UK or those with an established patient engagement programme in place?

Once you have a plan in place for the meeting, invite representatives from companies to join you. Some organisations have found it useful to invite an external facilitator to lead and chair this kind of meeting.

Invite representatives from individual companies to meet with you

If your organisation already has industry contacts, ask them to meet with you to discuss patient engagement in their programmes. For example, your organisation may offer a Corporate Sponsorship package or other type of industry collaboration which could be further developed to offer PPI support. If you don't have existing relationships with industry, companies are generally very interested in engaging with patient organisations and they are likely to be interested in making their programmes more patient focused. Many pharmaceutical companies have a 'Patient Organisation Lead' or similar who will develop relationships with organisations and connect them to relevant parts of the company. Meeting this person would offer an opportunity to hear about the company's programme and what's in the pipeline (they are more likely to be more open about this in an individual meeting than the group scoping meeting suggested above). You can also tell them about your charity's work to support PPI in research and discuss whether this is an area where they would like to collaborate.

Attend events and conferences

In recent years a number of conferences have been initiated worldwide that focus on PPI in industry-led research. They are excellent ways to network, make connections and find out who is interested in PPI. Some have reasonable discounts for patient organisations, but can still be expensive. One possibility is to get in touch with the organisers and ask to contribute to the conference. If you have something you want to share you could be invited as a speaker or to join a panel session. This will often ensure there are no registration costs. A few examples of these types of conferences that take place in the UK and Europe are listed below – although this list is not exhaustive. Each of these conferences has been attended by members of the Charities Research Involvement Group.

- **Pioneering Partnerships: putting patients first** – a UK-based conference which is jointly organised by the Association of British Pharmaceutical Industry (ABPI), Association of Medical Research Charities (AMRC) and National Institute of Health Research (NIHR).

This annual conference aims to inspire the sector to build better relationships with patients and carers to create a more inclusive and relevant research environment

- **Patients as Partners, Europe** – this conference is usually held in London, organised by The Conference Forum. The conference is co-produced with industry, patient advocates and government. It aims to help participants to implement and advance PPI in research.
- **Clinical Trials Europe** (formerly Partnerships in Clinical Trials) – organised by Knect365/Informa and held across Europe. This conference is held over three days. Days two and three are usually the most relevant, with a ‘Patients as Partners’ stream and a ‘Patient recruitment, retention and engagement’ stream. There are usually a number of projects from the UK represented here.
- **eyeforpharma** – an organisation holding conferences and events worldwide. Its annual conference in Barcelona provides a hub for senior-level industry executives, patient advocacy groups and other health experts to exchange ideas and stay up-to-date. eyeforpharma also holds an annual European patient summit which is developed in partnership with patients.

Your organisation may also regularly have a presence at conferences that are specific to the health condition you support. If this is the case, there will likely be representatives from industry active or interested in your area that may be worth approaching to discuss support with PPI.

Keep an eye out for conferences displaying the ‘Patients Included’ logo. This logo demonstrates that conferences have met the Patients Included criteria and that their events are committed to incorporating the experience of patients as experts in living with their condition, whilst ensuring they are neither excluded nor exploited.

In Ireland, the Irish Health Research Forum, attendees of which include patient organisations and industry representatives, has focused some of its events on PPI. Events managed by the Irish Platform for Patient Organisations, Scientists and Industry (IPPOSI) also offer opportunities for networking between patient organisations and industry.

Join an international PPI consortium

Patient Focused Medicines Development is a consortium of pharmaceutical companies, patient organisations and other organisations (e.g. National Institute for Health Research, and Health Technology Assessment international) interested in PPI. Being a member of this kind of consortium brings a number of benefits:

- It's a platform which can be used to raise awareness of your work nationally and internationally.
- It can increase your network and contacts at potential partner companies.
- You are able to shape the landscape of PPI alongside international partners.
- You have access to the latest resources and PPI initiatives internationally.

Membership is free for patient organisations – it just requires a commitment to contribute to their work. If you would rather not commit to becoming a fully-fledged member, you could choose to get involved with one of their projects. This could help you to learn more about industry-led research and to make useful contacts.

What do you want your relationship with industry to look like?

Choosing the type of relationship you have with a company will depend on how you currently support PPI and what the resource capabilities are within your team.

Some things to consider include:

- Do you offer a hands-off matchmaking-type service (putting research teams in touch with PPI contributors or simply sharing PPI opportunities with your network) or do you take a more hands-on approach to supporting involvement (such as supporting research teams to plan and deliver PPI)?
- Do you have time and resource in your team to support the planning and delivery of an industry-led project?

- Does the company have a dedicated patient involvement/ engagement lead, or is the involvement being managed by the leader of the research project? This could have a big impact on the time/resource the company is able to commit and will impact how you work together.
- If you are considering a 'service-type agreement' are you able to deliver all aspects of the work and what are the consequences if you do not deliver it to time and target?
- How much control over and input into the project would you like?

Examples

Asthma UK offered ad-hoc support with PPI to a number of pharmaceutical companies with no contracts and no financial support. It supported these projects (e.g. attendance at committees/panels/events) by posting the opportunities to its volunteer network of people affected by asthma. Volunteers could register their interest either by contacting the company directly, or via Asthma UK.

"We want our Research and Policy volunteers to have as many opportunities as possible to take part in diverse and high-quality involvement activities. By sharing opportunities such as these, our volunteers have the chance to experience the research process of large-scale pharmaceutical companies and be involved in high-level discussions. Although we only share a few industry-based opportunities each year, they are usually very popular among the volunteers. We believe that facilitating patient involvement in industry increases the impact for both volunteers and pharmaceutical companies, and helps to drive Asthma UK's goal to stop asthma attacks and cure asthma."

Caroline Wijnblad, Research Partnerships Officer, Asthma UK

Parkinson's UK set up a long-term collaboration with UCB, which involved a complex initial contractual process to cover multiple projects. The collaboration involved no financial remuneration from UCB (a pharmaceutical company) to Parkinson's UK. The two organisations worked together to plan, carry out and evaluate involvement activities. Parkinson's UK also invested financially in the projects, for example by covering PPI contributor expenses and the cost of an external facilitator.

“We wanted this to be an equal partnership, where both organisations take a lead in decision-making and planning for involvement. This has required a significant time investment from both organisations, but we recognise that we each have different areas of expertise and we are learning from each other.

Ultimately I believe this way of working has enabled us to ensure that we are involving people affected by Parkinson’s in the best ways possible, and that involvement is having the greatest impact, for the research and for everyone involved.”

Natasha Ratcliffe, Research Involvement Manager, Parkinson’s UK

Versus Arthritis (previously Arthritis Research UK) and Pfizer set up a research collaboration which involved the pharmaceutical company funding a small number of projects, including one focused on PPI. Both organisations worked together to plan and organise a workshop with people affected by arthritis to give their views on a clinical trial protocol.

Legal agreements between industry and your organisation

If you have agreed to work with a company, the process of setting up contracts can be intimidating, particularly if your own organisation does not have a legal team in place. The Association of Medical Research Charities (AMRC) has produced some excellent guidance about charities working with industry (in a broader context than just PPI).

The guidance clearly sets out what you need to think about when forming the agreement and strongly recommends that the finalised agreement is checked by a legal advisor to ensure the language and content is suitable before signing.

The AMRC guidance suggests that the main elements to consider when setting up an agreement include:

- Defining the partnership or collaboration
- Confidentiality
- Research activity to be performed including timescales of the research
- Budget and financial considerations
- Intellectual property (IP) rights

- Publications
- Conflicts of interest
- Exploitation
- Working with other partners and exclusivity clauses
- Limits of liability
- Acknowledging support

Other organisations that have set up legal agreements with companies to support PPI in research have given their top tips:

- Contracts are complex and can take a long time to sort out. Get legal support. Start early, and, if possible, get legal teams talking to each other from the outset.
- There can be the perception that industry is being inflexible and that charities are not diligent enough. Both these views can be true, but not necessarily. There can and should be compromise in the partnership.
- Be clear about intellectual property, communication and publication and include details of each in contracts e.g. who owns any reports produced and any other information on impact? How will outputs be shared with the wider community?

4. Planning a PPI activity with industry

In this section we discuss some areas that should be considered when planning and delivering work with industry.

Ask the company to complete a project brief/scope of work form

This will form the basis of the project and allow you to assess whether the company's proposal is something you are able to support. It will also help you to identify any questions you have. You may already be using a similar form for supporting academic researchers which can be altered to be more specific to industry.

Once you have received the form, you can set up a call to discuss your questions and, together, build a more comprehensive plan.

Come to a shared understanding of what PPI means

In deciding to work with a company you should have already considered its ethos, reputation and commitment to PPI.

But PPI itself may still be a fairly new concept to some companies. Their perception of PPI may be different to yours. Even those companies who have done some PPI before may need support and guidance.

"It's crucial when working with industry to ensure that we do not act as the representatives of autistic people but as the enablers of dialogue between them and industry. We need to avoid the risk that charity staff sitting on committees is perceived as sufficient by industry partners, when it should be the first step towards proper involvement".

James Cusack, Director of Science, Autistica

You may also find that a company is already a significant way into the development process before it approaches you for support with PPI. Although PPI has most impact when it is done from the very beginning of the research process, it is important to remember that if it is planned

well and delivered meaningfully it can have an impact at any time. Even a small change can make a huge difference to people with health conditions and their families.

Identify a lead person in each organisation

For continuity and clarity, it is important that both organisations have a lead person (if you are supporting more than one PPI activity, then a lead for each individual project). They will work together on all aspects of the project, regularly touching base with each other by email, online meetings and telephone. The leads should be jointly responsible for delivering the PPI activity. Their responsibilities should be agreed upon and clear from the outset of the project.

Working with industry on PPI can be different to working with academic researchers. A pharmaceutical company is likely to be much more corporate and complex, with global departments, in-depth processes to follow and regulator rules to adhere to. It's important to take the time to understand, where possible, how each other operates. Be understanding, prepared to negotiate and willing to compromise, whilst always being clear about what you cannot do (for example, this could relate to resource or your policy).

Ensuring that this relationship is a positive one will have huge benefits for the project. It's also important to remember that you are coming from different sectors and have different viewpoints, different codes to abide by and you do not fully understand the working ways of the other. If something doesn't seem to be working or frustrations are beginning to build, or if an element of the project doesn't make sense - just ask and prepare to see things from a different perspective. Your counterpart may be equally perplexed by how the charity sector works!

Ensure the team doing the research is involved in planning and delivery of the PPI activity

Consider whether the company you are planning to work with is fully committed to listening to, learning from and working with patients to ensure that its programmes are more relevant.

Whilst the pharmaceutical industry often contracts out delivery of elements of its work (i.e. Contract Research Organisations (CROs) deliver clinical trials), for PPI to be meaningful it should not be outsourced.

The project lead you are working with may not be part of the research team (or whichever team is looking for input from PPI contributors). For example, their role may be to work with patient organisations in many different ways, so supporting PPI in research and development will not be the main part of their job. Therefore, it's important to ensure that the team specifically looking for input from PPI contributors (e.g. Research & Development, Medical Affairs, Market Access) is involved in the planning and delivery of the PPI activity. The team will be able to work with you to decide what the aims and objectives of the PPI activity are, to plan the project, and work with you to produce information about the activity or research in plain English. It should also work directly with the PPI contributors.

Agree what the involvement activities will look like

The medicines development process at a pharmaceutical or biotech company can be complex. It's difficult to know where PPI contributors can become partners. The European Patients Academy (EUPATI) is a pan-European consortium focused on educating and training people affected by health conditions to ensure they can meaningfully contribute to medicines development (www.eupati.eu).

EUPATI has developed a helpful diagram (Figure 1) which displays different ways in which PPI contributors can be involved in industry-led research. This could form the basis of planning your PPI activities and help you in considering what methods best support the activity.

Patient involvement in medicines R&D

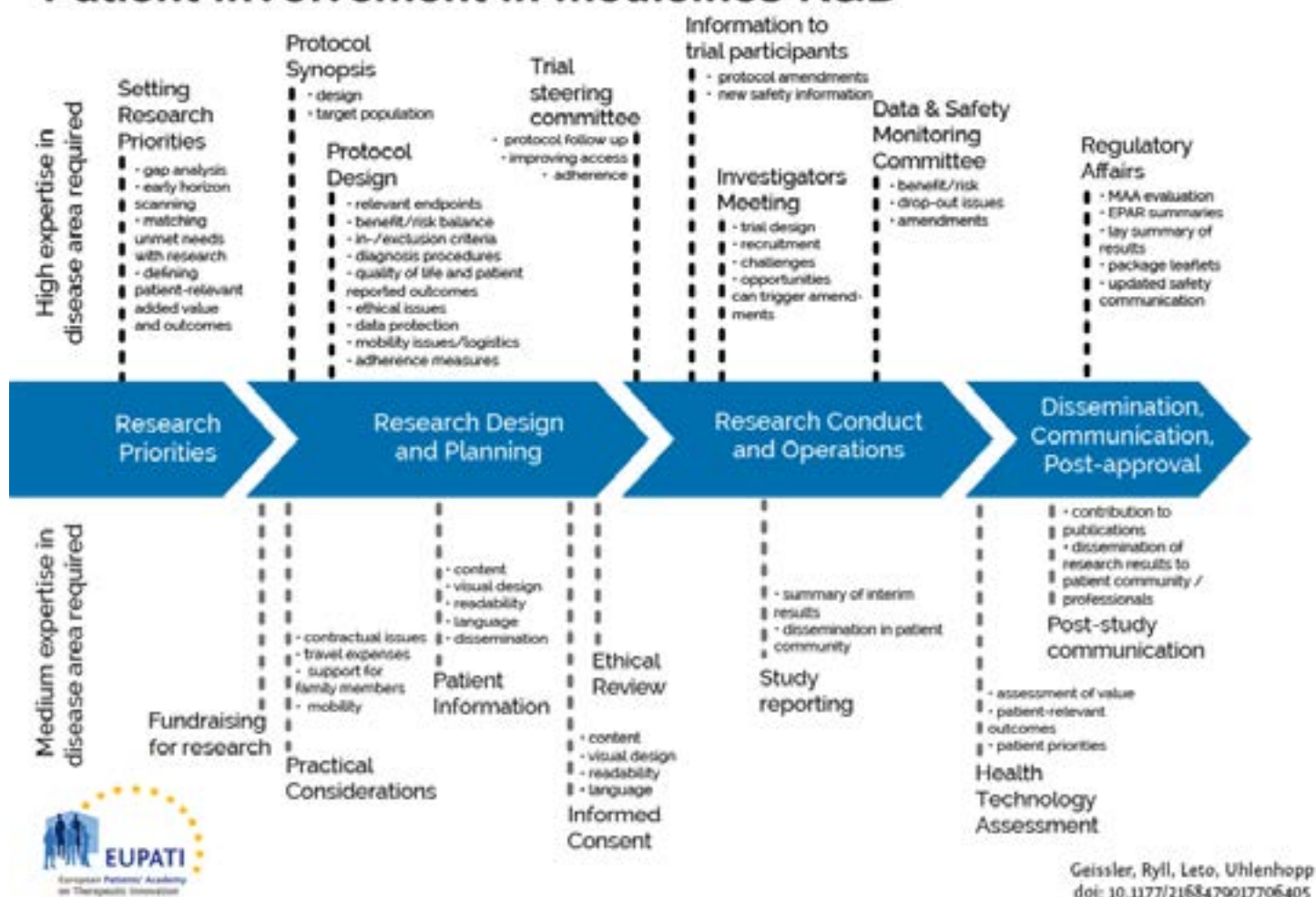


Figure 1: EUPATI Practical Roadmap of where in medicines development PPI contributors can get involved

When supporting industry with PPI, the methods you use are likely to be very similar to the way you may have already supported academic research. This includes:

- An ongoing role – for example, sitting on a steering committee for a trial.
- Organising a one-off discussion group or workshop to discuss outcome measures or unmet need.
- Supporting PPI contributors and a company to work together using email to develop patient information sheets and consent forms.

Agree standards

Your organisation may follow certain standards or have policies or working practices in place about involving PPI contributors. The company may have much less experience of actively involving patients and may need support to ensure that the PPI activity is planned and delivered to the highest standard. There are a number of resources that can be used by your organisation and the company together to ensure that you consistently work to the same standards. These include:

UK standards for PPI

In the UK, the NIHR worked with members of the public, the Chief Scientist Office (Scotland), Health and Care Research Wales and the Public Health Agency (Northern Ireland) to produce a set of standards which aim to provide people with clear, concise benchmarks for effective PPI, alongside indicators against which involvement can be monitored. See NIHR Standards

Patient Focused Medicines Development Quality Guidance

Patient Focused Medicines Development (PFMD) co-developed the Patient Engagement Quality Guidance with a large community of stakeholders representing patient associations, industry, academics, researchers and external experts. The guidance can be used to plan and deliver a PPI project that takes place at any stage in the research process. See Patient Engagement Quality Guidance

Agree how much time and resource each organisation will commit

The amount of time and resource you both agree to contribute towards the project will be dictated by the way you have agreed to work together. If you are supporting the company in an ad hoc way, it is likely that it will do the majority of the work and you will be a conduit to patients. If you are delivering the work as part of a Service Level Agreement, it is likely that the company will provide the costs of the project and you will provide the majority of time and expertise in delivering the PPI activity. If this is a joint collaboration, it is important to agree the time you and your co-project manager will both contribute to the planning and delivery of the activity.

You should also agree on who pays for what (see section [‘What do you want your relationship with industry to look like?’](#)).

If the company is covering costs for the venue and catering, a good but modest venue and menu choice which meets all accessibility or special requirements that may be needed is essential. It may also be helpful to explain the expenses associated with good quality PPI e.g. the need to cover costs for a carer, or to allow extra travel days and accommodation for patients who experience fatigue. These are all valid costs, but the company may not have experience in this area and may need reassurance from your organisation that costs like these are appropriate and justified.

Plan for lengthy industry processes

Each company will have legal and compliance departments working both globally and locally to ensure that all activities meet requirements of respective codes of practice (i.e. ABPI, IPHA, European Federation of Pharmaceutical Industries and Associations; EFPIA). For this reason, it’s likely that all externally facing documents (i.e. project plans, contracts, emails to recruit PPI contributors, pre-read materials, presentations or reports) will first have to be approved by these departments. This process can take weeks. And whilst many companies are working hard to simplify and speed up their processes to support better PPI, it is still worthwhile ensuring that you make allowances for these kind of delays in your project planning.

Consider working with external professionals

If the PPI activity involves bringing a research team together with patients for a meeting(s) (face-to-face, online or teleconference), consider working with external professionals. You could work with a facilitator who is independent and experienced in bringing together patients with researchers and/or health care professionals to plan and deliver the activity. This will allow you time to focus on ensuring the project is a success, that the individual and group needs of the patients involved are met and that you have an opportunity to get involved in the discussions if appropriate.

If you are having a face-to-face meeting and budget allows, you could also consider bringing in a professional writer to produce a report for the patients who get involved, your organisation and the company. Working with an external professional to do this will ensure that more of the discussion is captured and that there is minimum bias in what is written up. Involve the writer in aspects of the planning and be clear about what you want to capture. If you are planning to record the meeting you will also need to gain written consent from the participants.

Plan for how you will capture and share the impact of the PPI

View from a PPI contributor:

"It's difficult to know what you are able to share outside of the PPI activity. I have experienced giving a presentation on my involvement with a pharma company which meant talking about the protocol and changes made to it and discussions about process. Who does the knowledge belong to? When is it OK for me to share this?"

Jane Taylor, PPI Contributor, Versus Arthritis

In industry, there is general acceptance that for PPI to become a business-as-usual activity in medicines development, impact must be assessed, and a return on investment must be clear. Capturing impact to showcase the importance of PPI has also become an increasingly important area for charities.

Sharing experience and best practice is essential if we are to increase PPI in industry-led research. Ensuring that you capture the experience, lessons learned and impact from the perspective of all stakeholders is key. As part of the planning process, work together with the lead at the company to decide the best way to do this. It is also worth considering, perhaps at contract stage, who will own the results and how you will share them. Ensuring that all stakeholders, including PPI contributors, are aware of what can be shared is essential.

EUPATI has been collecting case studies of pharmaceutical companies working with patients and patient organisations in research. To access these case studies, visit www.eupati.eu and search for 'Patients Involved'.

Recruiting people to involve

Recruiting people to be involved in industry-led research can be more difficult than academic research. Whilst many PPI contributors have received training on the research cycle and how a study is built, the wider process of developing new medicines is complex, and can be intimidating and a barrier to involvement ([Drug development, the journey of a drug from lab to bedside](#)). Be clear when advertising the opportunity that they do not need to fully understand the medicines development process to contribute. Also be clear about any steps you will take to prepare them to contribute (see Preparing people to work with industry). Some patients may not want to work with industry on principle (see Do you understand your supporters' attitudes to working with industry?). If this is the case, you will need to find a way of recording it so that you do not invite them to take part in this type of activity again. Other patients may choose not to be involved because their involvement could preclude them from participating in the research or stop them being involved in other parts of the medicines development process (e.g. in regulatory decision making).

Some companies may have a particularly rigorous compliance process which may mean PPI contributors have to be publicly declared. This may deter some people from getting involved. If a company does have a rigorous compliance process, and this compromises the quality of the PPI, try to negotiate. If changing the process does not contravene the ABPI Code of Practice, the company may be prepared to be flexible. Remember to read the code and accompanying sourcebook (see ABPI Code of Practice) which may help you to understand what is a requirement within the code and what is more likely to be a company being risk averse.

Views from PPI contributors - recruitment

"PPI contributors need to be selected with the appropriate background, enthusiasm, experience and knowledge to fulfil that role."

"The charity representative needs to ensure, in so far as possible, that all the selected PPI contributors are likely to be able to meet deadlines, attend agreed meetings (face-to-face or remote) and to be committed to the work."

Combined quotes from various PPI contributors

Companies may feel that a narrow criterion for recruitment to involvement opportunities is necessary in order to mirror the criteria for participation in any proposed research. This way, any views expressed or experiences shared that may lead to changes carry more weight and are relevant to the population. However, you may want to involve as diverse a range of PPI contributors as possible. Discuss all of this in advance with your project co-lead and agree a role description and person specification.

Who will be the main contact person for this activity? Will it be someone from your organisation or from the company or both? How will this be managed to avoid confusion? Will this take extra time?

Build in time for:

- Compliance departments approving all recruitment information.
- Delays with recruiting people to involve.
- Delays with the process of contacting and confirming PPI contributors.

Payments to patients

PPI contributors who are involved in charity research involvement programmes will usually be offered full reimbursement of their expenses. Patients who are involved in NIHR or other public sector funded research can also expect to receive a modest honorarium for activities such as face-to-face meetings, in line with **INVOLVE guidelines**.

Fair Market Value

When working with industry, it is now increasingly accepted that, as well as fully covering expenses, it is also essential to pay for lived expertise. It is therefore strongly recommended that the company offers PPI contributors financial reward for their time and expertise. This may be something you consider writing into your policy or making companies aware of in the initial stages of talks.

There is work ongoing around Fair Market Value when it comes to involving patients in pharmaceutical medicines development. Currently there are no definitive guidelines for how much PPI contributors should be paid. Companies should offer compensation

commensurate with the expertise being provided. If a patient has significant expertise of their condition but also of the experience and management of the condition in many other patients, and they understand the drug development/regulatory process, then they should be seen as an “expert patient” or a “patient opinion leader” and the Fair Market Value should reflect their level of expertise.

Until more detailed guidance exists, take each project as it comes. Consider what is involved, how long the project will last and how much preparatory work needs to be done. Work with the people you’re involving and the company to agree a fair amount. Be clear on when the payments should be made, depending on the type of involvement activity. For example, if the work is ongoing, should PPI contributors expect to be paid up front, in instalments or when the project is complete?

It’s also important to be clear with PPI contributors about the potential implications of taking payment on their tax contributions and any benefits they may receive. If PPI contributors have concerns about their tax contributions or benefits, be clear about where they can go for advice.

View from a PPI contributor: payment

“When I got involved in a pharma project I and other patients were given financial remuneration for our input. Despite INVOLVE guidelines, this is still non-standard practice in patient involvement and however committed you are to the cause, chronic illness makes you poor. So this was a positive for all the patients I spoke to.”

Jane Taylor, PPI Contributor, Versus Arthritis

Hospitality and venue choice

There are strict rules around the pharmaceutical industry providing hospitality. These rules cover meeting venues, hospitality, subsistence and travel expenses. In short, these should not be extravagant, they should reflect a level which the recipients would normally adopt when paying for themselves. There are also strict rules around the type of venue that a company can attend, so discuss this fully with your project counterpart.

Paying for an accompanying carer

Whilst paying for a person to accompany a member of the health profession is prohibited, the provision for a carer to accompany someone with a disability is allowed. This should be discussed and agreed in advance with the project lead at the company and made clear to any potential PPI contributors who may need this extra support. You may find that you need to act as an advocate to justify this cost as an essential part of good PPI, as this may not be something that the company has done before.

Is it possible to be involved and not receive payment?

Some PPI contributors might wish to decline receiving a payment from a company. Companies may have their own individual policy on zero-fee contracts, which could include insisting that a fee is necessary. Under the UK ABPI Code of Conduct there is no requirement for a PPI contributor to receive a fee, so there may be room to negotiate with the company on this point.

In conclusion, whatever decisions are jointly made around payments and hospitality, remember that transparency and openness are key.

Contracts for patients

There are a number of factors that determine what a contract or agreement between a company and PPI contributors might look like, including the company's policy, the nature of the involvement activity and whether your organisation has an existing confidentiality agreement with the company. EUPATI suggests as a minimum that a written agreement should clearly define:

- A description of the activity and its objectives
- The nature of the interaction during the activity
- Consent (if relevant)
- Confidentiality
- Compensation
- Data privacy
- Compliance
- Declaration of conflict of interest
- Timelines

Contracts or written agreements for PPI contributors are often written from the company perspective. The PPI contributor must abide by the elements in the contract (confidentiality, intellectual property etc.). It is helpful to create a more balanced agreement that sets out the expectations of both parties (the company and PPI contributor). This could include the roles of all stakeholders and shared working practices i.e. the nature of interaction and minimum standards to be expected from all stakeholders. For example, the PPI contributors can expect a minimum of one week will be given for any preparatory reading, a notice period of one week for any meeting, and feedback to be provided within an agreed amount of time (this will vary if waiting for a report to be prepared and approved).

View from a PPI contributor – contracts

“The contract process was burdensome and complex. It was difficult to scan and return the document quickly if you didn’t have access to professional office infrastructure. With one project I work on, the contracts were brought to a starter meeting where there was a pharma compliance person to discuss anything and streamline the process. This was really useful.”

Jane Taylor, PPI Contributor, Versus Arthritis

A European multi-stakeholder project, led by Myeloma Patients Europe, has developed guiding principles for [Reasonable agreements between patient advocates and pharmaceutical companies](#) which aim to make legal agreements between both parties easier and more acceptable. They also provide the baseline for the development of contracts and contract templates, as well as a toolbox for patient advocates and companies.

Confidentiality agreements

If no other contract or agreement is necessary, PPI contributors will likely be asked, at the very least, to sign a confidentiality agreement. This agreement, also known as a non-disclosure agreement (NDA) or confidential disclosure agreement (CDA), is a legal contract through which two or more parties agree not to disclose information covered by an agreement. They are common in industry.

There may be some instances where it is not appropriate for PPI contributors to sign a confidentiality agreement (for example, children or people with learning disabilities should not be asked to sign such an agreement). Or you may like to ensure that no risk of breaking confidentiality is placed on the PPI contributors. If this is the case, explore whether you can tailor what is shared with the PPI contributors to be more general, or avoid mention of any information that may pose a threat to intellectual property if it is shared.

Preparing people to work with industry

As with most PPI activities, when supporting PPI in industry research your contributors are likely to have different levels of experience and expertise. This may not be an issue when recruiting to academic research. However, in industry-led research processes, terminology and ways of working can be particularly complex and potentially intimidating. It is essential to ensure that the PPI contributors know what to expect and feel fully prepared to contribute to the work.

Views from PPI contributors – preparing PPI contributors

“All meetings need to be conducted in plain English – if a PPI contributor does not fully understand what is being said it is demoralising and does not encourage participation.”

“PPI contributors need to have a clear understanding of the whole pharmaceutical research process and most importantly the benefits for them overall – a presentation by the company may be useful.”

“Training is important for the selected PPI contributors to prepare them for their role.”

“Clear information and expectations are really important. Where they have worked well it helped me prepare for the day logistically in terms of travel etc. but it also enabled me to think about how I could best use my experience in the workshop.”

Combined quotes from various PPI contributors

It is likely your programme already follows good practice in PPI, such as ensuring that PPI contributors are given ample time to read preparatory documents and that all documents are prepared in plain English.

Additional ways charities have prepared their contributors include:

Organising a group introductory call before the PPI activity

When Parkinson's UK worked with UCB to bring together 15 people affected by Parkinson's for a clinical trial workshop, it helped prepare PPI contributors by holding a pre-meeting videoconference to introduce PPI contributors to each other. This helped to break the ice and made them feel that they were not joining a group of strangers on the day of the workshop.

Training

There are a number of charities that offer training to PPI contributors. For example, Asthma UK, Cancer Research UK and Marie Curie together with other charities hold joint PPI training sessions to prepare PPI contributors to be involved in research. The HRCI is currently partnering with Trinity College Dublin to develop generic training that can be adapted by anyone wishing to deliver an 'Introduction to PPI' workshop. Training sessions like these sessions usually include an introduction to PPI, how a research study is built, and activities/examples of how PPI contributors can improve research. This training gives a good basis for contributing to industry-led research. However, when the PPI activity is more involved or covers a more complex subject, extra training and/or support may be necessary.

Example

Parkinson's UK worked with Parkinson's Foundation in the US and UCB to bring together a team of six people affected by Parkinson's to advise UCB on a project to develop more relevant outcome measures in Parkinson's.

To adequately prepare the group, Parkinson's UK, Parkinson's Foundation and UCB created three 'journal club' sessions exploring outcome measures and patient involvement in outcome measures development. They also organised a video training session on outcome measure development and recorded it so the group could watch it again if needed.

EUPATI currently offers two levels of training for patient advocates:

- **EUPATI Patient Expert Training Course** – a European comprehensive 14-month training programme offering expert-level training in medicines R&D
- **EUPATI Toolbox** – an online resource of information about medicines R&D

It also has a number of guidance, publications, webinars and case studies available to support people to better understand the pathway to new medicines and how PPI contributors can meaningfully contribute to the medicines development process. An aligned programme in Ireland, the [Patient Education Programme](#), is delivered by the Irish Platform for Patient Organisations, Scientists and Industry (IPPOSI)

Managing expectations of your PPI contributors

When recruiting your PPI contributors to a PPI activity that involves the development of possible new treatments, you may need to spend a significant amount of time and effort to ensure that you properly manage the expectations of those people involved.

Research can bring renewed hope for cures or life changing benefits. Be absolutely clear that your PPI contributors understand their role and that their involvement does not mean they will have access to the clinical trial or potential treatment.

5. Feedback, follow up and next steps

Giving feedback on the outcomes of the project is accepted as one of the most important aspects of PPI, yet it remains an area that is often overlooked. Before you agree to work with or support a company with PPI, ensure the PPI contributors will get feedback about their input and what was changed as a result. As with many other aspects of industry-led research, this can take time. Have a realistic plan in place for sharing feedback and ensure that the PPI contributors are aware of this timeline and that there could be delays. As a minimum, as soon as possible after any PPI activity you should report back on what was discussed and any short-term impacts. It is also important to ask for feedback from the PPI contributors about their experience of being involved.

Be prepared to follow-up with the company to make certain that feedback and impact is shared. If there are delays, you may need to do some chasing and keep PPI contributors in the loop. They generally will not mind delays - the most frustrating thing for them is not hearing anything.

Feedback from PPI contributors about their experience of being involved as well as giving and receiving feedback about the successes and challenges of working together with companies is also an important part of the process. This will undoubtedly improve the success of future collaborations and ensure that PPI contributors have the best possible experience of being involved.

Once the initial involvement activity is complete, can you explore opportunities for further involvement? If you have supported a company with bringing together PPI contributors for a one-off meeting to discuss a trial, is there an opportunity for those contributors to also work with the company on other aspects, such as patient information sheets and consent forms, to advise them on aspects of recruitment or to be part of the trial steering committee? This way, involvement can become more ingrained and potentially more meaningful and impactful.

Finally, sharing how we are working with industry and the impact of PPI is essential. By working together in this way and ensuring patients are at the centre of medicines development we are helping to change the way medicines are developed. But, as always, progress takes time so we must share our experiences, the benefits and challenges, so that others can be encouraged to work together to find new, better and more relevant treatments for the people who need them most.

Resources

Helping you develop your policy and approach to working with industry

ABPI – National Voices: [Working together, delivering for patients](#)

Autistica: [How we choose partners](#)

Health Research Charities Ireland (HRCI): [Code of Practice](#)

AMRC: [Guide to charities working with industry](#)

'Working with industry' policy documents from UK charities

[MS Society](#)

[Bloodwise](#)

[British Heart Foundation](#)

[Prostate Cancer UK](#)

Industry Codes of Practice and related materials

ABPI (UK): [Code of Practice](#)

ABPI (UK): [Sourcebook](#)

IPHA (Ireland): [Code of Practice](#)

EFPIA (Europe): [Code of Practice](#)

EFPIA (Europe): [Working together with patient groups](#)

Resources for PPI in pharmaceutical research (standards and training)

EUPATI: [EUPATI Toolbox](#)

IPPOSI: [Patient Education Programme](#)

NIHR Standards [NIHR Standards](#)

PE Quality Guidance [Patient Engagement Quality Guidance](#)

Article: [Drug development, the journey of a drug from lab to bedside](#)

Transcelerate Biopharm: [Patient Protocol Engagement Toolkit](#)

Payments to PPI contributors

INVOLVE: [INVOLVE guidelines](#)

Contracts

Myeloma Patients Europe: [Reasonable Legal Agreements](#)

Appendices

Case study 1

PPI contributor's perspective on working with industry - Jane Taylor

The thoughts I have set out here come from my involvement with pharma as a patient giving information and patient expertise at three single events with different pharma companies, two in the UK and one in Germany. I also chair a patient group working on a five-year European Innovative Medicines Initiative (IMI) 25-centre funded project which has three drug companies involved and so my relationship with these companies is ongoing. I have summarised here the key positives and negatives I have experienced as a patient, as well as some ideas for charities to think about in relation to involving PPI contributors in working with pharma.

Contexts

My input has taken different forms: an afternoon workshop advising on a phase 4 trial, a day long workshop on issues in the treatment of psoriatic arthritis and a research and development day on arthritis in Germany. The first two were organised and jointly facilitated by pharma representatives and Versus Arthritis staff. The third was organised directly between the company and myself. I have also worked with three pharma companies on the APPROACH project on Osteoarthritis. As a patient I have generally found these experiences worthwhile and positive overall.

Positives

- **Clear information and expectations:** This is really important and where it worked well it helped me prepare for the day logistically in terms of travel, etc., but it also enabled me to think about how I could best use my experience in the workshop. Contact details of a key pharma contact who was involved helped also, as charity staff are obviously not always around immediately preceding an event. Having a phone number of the pharma facilitator was useful.
- **Clear focus in the sessions:** I personally found the sessions where I was involved in a specific focused activity such as commenting on a protocol or patient information more useful than a general “improve pharma’s understanding of the disease”. So the most useful session for me was where there was a specific task or tasks to advise on. For example with the phase 4 trial workshop they wanted patient involvement to understand some of the issues in a phase 4 trial of a drug, so expectations were clear and the afternoon was very focused.
- With the R&D day in Germany, I was sent a list of questions to think about in advance. Although we obviously deviated from this considerably, I found it very useful. For the treatment of psoriatic arthritis session, it was more unfocused and was about the patients’ general narratives. Knowing in advance what the focus is going to be can help a patient decide more clearly if they want to be a part of this.
- **Feedback:** It is important to hear how the outputs of the day have been used or what was most useful about the session. This is rarely done in PPI. Feedback on the day was positive from all three sessions but only one of the pharma companies gave specific feedback on changes it was making as a result of patient input. For example - changing specific language in the information sheets, incorporating infographics for complex information, reducing number of questionnaires in protocol, introducing a fatigue measurement, etc. As far as I am aware we were not asked to give feedback on our experience of the sessions. Feedback, in my opinion, should always be a two-way street.
- **Payment:** I and other patients were given financial remuneration for our input. Despite INVOLVE guidelines, this is still non-standard practice in patient involvement and however committed you are to the cause, chronic illness makes you poor. So this was a positive for all the patients I spoke to.

Negatives

- Time planning: With two of the experiences everything was rushed at the end. There was a delay in the actual date confirmation. Contracts had to be signed by patients before information about the day could be sent out.
- The contract process was burdensome and complex. It was difficult to scan and return the contract quickly if you didn't have access to professional office infrastructure. With the European project I work on, the contracts were brought to a starter meeting where there was a pharma compliance person to discuss anything and streamline the process. This was really useful.
- Compliance Process: The ABPI Code of Practice prevents industry promoting products or influencing patients. Involvement of patients is often suspect and associated with promotion of a company's products. This can make the pharma representatives nervous of ensuring compliance. At the treatment of psoriatic arthritis day, we couldn't actually mention by name the drugs we were on - only the type of drug - for example, an immunosuppressive or a TNF inhibitor. This became difficult as a couple of sessions were about sharing our treatment journey in small groups and then as a wider group and inevitably some drugs got mentioned!
- Communication related to compliance: It is also difficult to know what you are able to share outside of the meetings. I have experienced this giving a presentation on my work with APPROACH which has meant talking about protocol and changes made to it and discussions about process. Who does this knowledge belong to? When is it okay for me to share this?

Case study 2

Autistica's involvement in AIMS-2-TRIALS

What was the purpose?

AIMS-2-TRIALS is a public-private partnership between universities, members of the European Federation of Industries and Associations (EFPIA), small and medium enterprises (SMEs), non-profit and charity partners. The members of EFPIA involved are Roche, UCB, Jansen, Teva, Novartis.

AIMS-2-TRIALS received €55m from the Innovative Medicines Initiative (IMI) and in-kind support from pharmaceutical companies, SMEs and charity partners bringing the total cost of this project to an estimated €113m. None of the grant received by the IMI is paid to the pharmaceutical companies or the charity partners.

The aim of the project is to better understand how autism develops from childhood through to adulthood, to find biomarkers¹ for autism, to test medicines and to build a Europe-wide clinical research network.

Why collaborate?

In the past there has been a real disconnect between researchers and the autism community because research has not focused on community priorities and has often happened without the involvement of autistic people. This has led to a suspicion around the motivations of research – resulting in many autistic people disengaging with research altogether.

For Autistica, AIMS-2-TRIALS represented an opportunity to begin to redress this imbalance by lending expertise in meaningfully including the voice of the autism community in the largest autism research grant ever awarded.

How are you collaborating?

Our Director of Science, Dr James Cusack sits on several of the committees that guide the running of this project. Along with the University of Cambridge and Autism-Europe they have established a panel of autistic representatives (A-reps) who will guide the development of the project in relation to research ethics,

communication, policy development, developing appropriate outcome measures for trials and training researchers and clinicians across the consortium. We are currently in the process of recruiting A-Reps. A steering committee of A-Reps has already been set up to manage the recruitment and selection of further members.

Autistica have been advocating for community priorities, identified in our previous James Lind Alliance priority setting partnership in early stage meetings where project partners decide on the development of the project. This has included the selection of potential biomarkers and the development of an outcome measure that autistic people find acceptable to use as an outcome measure in a clinical trial. Autistica have provided access to our Insight Group to consult on the accessibility, acceptability and suitability of the AIMS-2-TRIALS website and on information letters and consent forms for the project.

Key impacts on the research

- Participants and the wider autism community have valid concerns that pharmaceutical companies are interested in autism because they are pursuing a cure for autism, this belief is distressing to autistic people (particularly in the rights movement) many of whom view their autism as an integral and often positive aspect of their self-identity.
- Testing the website, information letters and other communication materials for accessibility and acceptability will be important in successfully meeting recruitment targets.
- Involving autistic people and those advocating for them in deciding what is ethical is key in demonstrating the trustworthiness of this project to the community.
- The A-Reps involvement in deciding on possible biomarkers and on the suitability of outcome measures for trials will likely improve the utility of this research as well as ensuring research priorities and community priorities are aligned.

Challenges

Joining this initiative presented some significant challenges to Autistica. Primarily, these difficulties stemmed from the short amount of time available to the charity to decide about being involved and the need to make this decision without community consultation. The decision was taken without community consultation in this instance because the details of the project were strictly confidential and we did not, at the time the decision was taken, have a governance structure in place that could guide our decision making process about how we chose partners to work with that would allow us seek consultation from community representatives without breaking our confidentiality agreements.

When the project was announced, several members of the autistic community were vocal about their concern and a few rallied against the decision and withdrew their support for Autistica. There was an automatic distrust for the project because a previous large-scale project run by the same lead researchers (EU-AIMS) failed to communicate their motivations effectively and was extremely negatively received. This led to misconceptions about the project that were difficult to remedy. That coupled, with the involvement of pharmaceutical companies and a charity in the US with a history of seeking an autism cure, meant that the project was always going to be a risky thing for Autistica to associate with. Our situation was not helped by the lack of consultation with the community. Through some careful social media communications, we managed to explain our position as a partner that would provide a platform for the community within the project to the majority, although some remain sceptical or strongly against the partnership.

Lessons learned

In response to this we have developed a **policy that guides our decisions about when and how to enter into partnerships**. This policy, alongside a standardised operating procedure, sets out Autistica's process for entering into partnerships based on the following nine questions:

1. **Is there evidence of community need (do some autistic people and family members want this)?**
2. **Is it novel? If we don't do it, will someone else?**
3. **Are we confident the activity/science will be high quality?**
4. **Are we confident that the activity is ethically sound (if research, approved by an ethics committee) and safe?**
5. **Are there any serious risks or reputational concerns?**
6. **What is the level of resource required and, if appropriate, are we being appropriately compensated for our time?**
7. **Does this comply with our partnership policy?**
8. **What is the impact of this work and how does it align with our charitable objectives?**
9. **Is the proposed activity sufficiently clear?**

If the answer to any of the following questions is unclear, our policy dictates the level of escalation (Autistica's Insight Group -> Senior Management Team -> Risk Committee -> Board of Trustees) that is needed to reach a decision.

1 Autism is diagnosed based on observations of people's behaviour along with people's reports about their current and past behaviour. For that reason, it is difficult to reliably and accurately measure and record autistic traits. A biomarker is a biological marker that could be accurately and reliably measured that could tell us about somebody's autistic traits, for example, measuring their brain activity during a task.

Case study 3

Parkinson's UK and UCB collaboration case study

The purpose of the collaboration

UCB wanted to explore how it could involve people affected by Parkinson's in its R&D programme and use patient insights to inform the development and testing of new treatments. Parkinson's UK had expertise in supporting research teams to work with people affected by Parkinson's, and so initially the two organisations met to discuss the different ways people affected by Parkinson's could be involved in UCB's R&D programme.

UCB was planning a potential phase 2 clinical trial to test a new medicine for the treatment of early stage Parkinson's, and the two organisations identified this as an opportunity for collaboration. The purpose of this work was for UCB to get feedback from people affected by Parkinson's on their plans for the clinical trial and gain valuable insights to help improve the trial design.

What we did

UCB and Parkinson's UK hosted a workshop to bring together people affected by Parkinson's and members of the UCB research team to discuss the clinical trial. The Research Involvement Manager from Parkinson's UK and the Patient Advocacy and Global Neurology Clinical leads from UCB worked together across several months to plan and deliver the workshop. Parkinson's UK identified people to be involved through its Research Support Network. Ahead of the workshop, attendees were given a number of pre-read materials to prepare them for the day. They were also invited to join an introductory video call where the purpose of the meeting was discussed and they were given the chance to ask questions.

The workshop was chaired by an external facilitator, and members of staff from Parkinson's UK and UCB (including members of the research team) facilitated discussions. A total of 15 people affected by Parkinson's (including carers and family members) attended. The workshop involved a mixture of short presentations, table discussions

and group Q&As. The first session was focused on general aspects of clinical trials and included a talk by someone with Parkinson's about their experience of participating in a clinical trial. The following sessions were focused on specific aspects of UCB's planned trial, including testing procedures, medication adherence and wearable devices. A medical writer recorded all discussions and produced two reports of the day – one which was shared with all attendees in the months after the workshop, and another more scientific version for internal use by UCB

Benefits and impact

For the research

The research team gained valuable feedback and suggestions for the planned clinical trial. People affected by Parkinson's advised on a number of important aspects which could improve trial recruitment and retention, including:

- What kinds of information newly diagnosed patients might need in order to consider taking part, and how long after diagnosis people should be approached.
- The importance of explaining what invasive testing procedures involve clearly to prospective participants in appropriate, easy-to-understand formats (including videos and booklets).
- How study site visits could be made easier for participants.
- How the medication packing could be changed to be more convenient for participants.

For UCB

The workshop provided UCB with a better understanding of what motivates and discourages people to take part in clinical trials more generally, and what prospective participants want to know when considering taking part in a trial. It also helped UCB to understand how it can involve people affected by Parkinson's in its R&D programme, and gave the team new ideas for how it could get patient input in other projects. Furthermore, the company gained valuable insight into the processes involved when working with patients and patient organisations.

For people affected by Parkinson's

Attendees commented that they found the workshop extremely empowering and uplifting. They felt like their views were listened to and valued. People also said the workshop made them more confident in participating in future clinical trial research.

For Parkinson's UK

The workshop demonstrated the importance of bringing together people affected by Parkinson's and a pharmaceutical company and provided Parkinson's UK with a great example to add to their portfolio of involvement support. The charity also learned a lot from the process which will enable it to further develop its involvement programme.

Challenges and learnings

Compliance processes

All materials related to the workshop had to be approved by UCB's compliance team, including adverts, the role description, invites to participants, pre-workshop materials, the workshop briefing and agenda, the presentation, the feedback survey and the final reports. This inevitably added time to the process and pressure on deadlines.

Payments

The workshop attendees received an honorarium payment. Initially it was suggested that UCB make a payment to Parkinson's UK, which would then pay people affected by Parkinson's. However, Parkinson's UK policy meant that it could not accept a payment from UCB. This required UCB to set-up individual agreements with the workshop attendees, which added a large administrative burden.

Contracts

UCB and Parkinson's UK decided to enter into a collaboration to jointly deliver the workshop. This complicated the contractual process, since it required more than a 'service agreement' between the two organisations. Initially the respective legal teams did not directly communicate, and instead contractual negotiations were handled via the Research Involvement Manager and Patient Advocacy lead. This delayed the process. It also took time to agree on how information would be shared and communicated more widely, since the considerations around this were more complex for UCB compared to Parkinson's UK.

Case study 4

Versus Arthritis (previously Arthritis Research UK) - Pfizer case study

The purpose of the collaboration

Pfizer wanted to gain a better understanding of what it is like to live with rheumatoid arthritis (RA), and how these lived experiences can begin to inform the efforts to develop medicines and support programs for people with RA. Initial collaboration took the form of insight gathering (determining study relevance and accessibility, patient-centred outcomes and appropriate approach to PPI) for a phase 4 study comparing current best practice treatment against a newly developed drug. Moreover, Pfizer also wanted to gather insights from the perspective of patients on the future role of patients within the decision-making of the study and wider company.

Versus Arthritis had partnered with Pfizer in the past in co-funding research projects and the direct experience of the charity's approach to meaningful integration of patient insight in those projects and our general expertise in the area, made the charity obvious collaborators for this activity.

What we did

Versus Arthritis' Research Involvement Manager and Pfizer's UK Scientific Lead in Inflammation worked closely together to develop, plan and facilitate a workshop in which people with RA would be invited to provide feedback on various aspects of the study and its design.

Attendees were provided with pre-read materials articulating the purpose of the workshop, the expectations of what we wanted to gather and achieve from the day and what they could expect from in terms of support. They were also provided with key pieces of information and sections from study protocol that would enable more focused and informed discussion on the day.

On the day, crucial areas of review and associated questions to be addressed formed the structure of discussion. Short 5-10 min

presentations were followed by group facilitated discussion, with notes taken by facilitators. The workshop was three hours long with a tea/ coffee break.

Notes were then written up and signed off by facilitators and attendees. This information was then provided to the study investigators to use to amend and enhance the study protocol.

Benefits and impact

There were clear areas of positive impact from gaining understanding from patients on the delivery of the trial itself. Pfizer asked that the specifics of the outputs remain confidential but they broadly included ideas on recording of symptoms and communication with study participants.

The charity found the collaboration very valuable and influential. Its aim is to make sure that the relevance to people with arthritis and quality of the research in the field, in any sector, is as high as possible, and believes the collaboration has effectively achieved this.

Challenges and learnings

This was the first time that either organisation had partnered on such an activity and so there were a number of challenges and useful learnings along the way.

Time

- Circumstances meant that the contracts and planning for the session were done relatively close to the workshop itself which rushed decision making. This meant that there were some issues/ inefficiencies on the day that could have been mitigated with more time and greater value could have been gathered from the workshop.
- Charities and industry work very differently and a bit of time spent early on agreeing timelines would have allowed us to work out what could be most effectively achieved in the time we had.

Compliance process

- The ABPI code of practice prevents industry promoting products to or influencing patients or patient organisations. Compliance teams within companies are very risk averse and will need a lot of information and time to understand and approve new documentation and approaches. They can also often conflate involvement with promotion and so prevent you from doing something on that basis.
- The code of practice is necessary to protect patients and so spending a bit of time understanding it and its purpose will allow you to articulate your documents and process documents that require compliance sign off more effectively. This can help to prevent misunderstanding and difficulties later on.

Legal process

- Industry legal process, procedures and documentation are very robust; charity approaches are often not. As such, there can be the perception that industry is being inflexible and that charities are not diligent enough.
- Both these views can be true but there can and should be compromise in the partnership. To protect everyone involved, charities should contact a legal expert to talk through the initiative to flag early issues or things to look out for. Industry partners should be open to greater flexibility, especially in simplifying and explaining legal documentation for volunteers.

YOUR NOTES



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