From Transactional to Truly Collaborative:

Improving Relationships Between Industry and Patient Organisations



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Terminology

Patient Organisations (POs)

This covers any organisation mainly comprising of patients and/or caregivers or any user organisation such as a disability organisation, carer or relative organisation and consumer organisation that represents and/or supports the needs of people living with health conditions and/or caregivers. (Association of British Pharmaceutical Industries; ABPI Code of Practice 2022)

Patient engagement

This has many definitions depending on where in the world it is used, and who is using it. The pharmaceutical and medical technology industry tend to use the term to describe Patient and Public Involvement (PPI). As we are approaching industry for their insights, we have used the term most familiar to them. So, for this report, patient engagement is when patients or carers meaningfully and actively collaborate in the governance, priority setting, planning and conduct of research, as well as in summarizing, distributing, sharing, and applying its resulting knowledge. (Adapted from the Canadian Institutes of Health Research, CIHR (2014))

Patient

'Those (people) having or at risk of having a medical condition(s) whether or not they currently receive medicines or vaccines to prevent or treat a disease' as well as 'the family and those caring for those with the medical condition(s), patient advocates, and patient groups.' (National Health Council, 2017)

Pharmaceutical companies

Discovering, developing, producing, and marketing medicines and vaccines for use as treatments for patients, with the aim to cure them or alleviate symptoms or vaccinate and prevent disease onset. Pharmaceutical companies may work in the field of innovative or generic medications, vaccines, and medical devices.

Medical technology (Med tech) companies

Every product, service, or solution using medical technology to improve people's health by preventing, diagnosing, monitoring, and treating disease.

Patients, carers, family members and/or POs

We use this term throughout the report, and hope this is an inclusive way to describe all people living with or impacted by health conditions as well as those organisations working to support them.

About This Project

This project was led by Versus Arthritis and seven other Patient Organisations (POs) in the UK: Parkinson's UK; Cystic Fibrosis Trust; Alzheimer's Society; Gene People; Alopecia UK; MS Society and Asthma and Lung UK.

The project aimed to:

1) Provide clarity about how pharmaceutical companies are working with UK-based patients, carers, family members and POs across the medicines development process, and how they want to work with them in future.
2) Help POs plan how they would like to work with pharmaceutical companies.
3) Encourage those in the pharmaceutical industry to consider how they improve their working relationship with POs.

The project included an initial literature review, a survey of pharmaceutical company representatives and a facilitated workshop. The aim was to gather views, attitudes, and examples of patient engagement activities across the medicines development process, from representatives with key functions in pharmaceutical companies. These included patient advocacy, research and development, medical and regulatory affairs, pharmacovigilance, market access, and any other department working, or interested in working, with POs.

The outcomes and recommendations aim to optimise collaborations between the UK pharmaceutical companies and POs. Stakeholders from industry, patients, carers, family members and/or POs worked in partnership to develop these recommendations. Whilst it is UK focused, our findings will be relevant for POs everywhere, particularly across Europe.

This project did not aim to report on patient engagement best practice and the importance of collaborations between industry and POs, which is already well covered in the literature. Exploring how POs are working with and/or want to work with the pharmaceutical and medtech industry may be a logical next step for further work but was also not covered here.

The project was funded by Versus Arthritis, Parkinson's UK and Cystic Fibrosis Trust. MediPaCe, a patient engagement provider, gave pro-bono support. The project had input from a range of POs, people living with health conditions and representatives from the pharmaceutical industry.

We would like to thank everyone involved in the planning and delivery of this project, particularly our fantastic steering group, who gave much more to the project than we initially asked of them. A list of steering group members is attached as Appendix A.

Thank you also to all those who completed the survey, joined us for the workshop, and those who shared case studies.

EXECUTIVE SUMMARY

FROM TRANSACTIONAL TO TRULY COLLABORATIVE

Improving Relationships Between Industry and Patient Organisations

Patient engagement in research is well established in the UK. A significant number of Patient Organisations (POs) in the UK involve people affected by health conditions in their research funding programmes and many support research teams to work with their patient communities to prioritise, design, deliver and disseminate research.

Patient engagement in research led by pharmaceutical companies is less consistent and, although this is changing, there is much work to do to understand how pharmaceutical and medtech companies are working together with patient, carers, family members and/or POs. This project aimed to provide clarity about how partnership working is being done across the medicines development process, and how this could develop in future. It hopes to help with planning and to encourage improved working practices.

The first step of the project was to conduct a review of literature. This revealed a lack of information about current working partnerships, focussing instead on standards of collaboration, aspirations, and case studies. This was followed up with a survey of pharmaceutical companies which received 52 responses from people working in a variety of roles and departments. Finally, a virtual workshop brought together a range of stakeholders to explore the survey results and develop recommendations.

Partner organisations

abpi

ASTHMA+ LUNG UK

BAYER

Cystic Fibrosis Trust

GENE PEOPLE
the genetic conditions support network

MediPaCe®
Making Patient Engagement a Reality

MS Society

PARKINSON'S UK
CHANGE ATTITUDES.
FIND A CURE.
JOIN US.

Pfizer

RESEARCH VERSUS ARTHRITIS

Key findings

- Our survey found that within companies, the functions that most commonly engage with patients and POs are Medical Affairs, Research and Development, and Corporate Affairs.
- Pharmaceutical companies reported that working with patients and POs was beneficial, especially in helping them to gain a better understanding of patients' experiences and unmet needs; in raising awareness and motivating staff; improving knowledge of healthcare delivery; developing more relevant outcome measures; and in informing strategic aims and direction. It was reported to have a significant impact on their work and on company decisions and direction.
- Patients and POs were involved throughout the medicines development process, but most commonly in the clinical research phase.
- Nearly two thirds of survey respondents said that they plan to increase their work with patients and POs in the UK over the next two years – aiming for long-term relationships based on partnership and co-creation. Over half were looking to run projects to better understand patient experience and need.
- Pharmaceutical representatives felt the most important role that POs could play is to sit alongside patients and carers to represent a range of experiences, as well as supporting the planning, management & delivery of engagement activities.
- Currently, varying interpretations and perceptions of risk from the ABPI Code of Practice in pharmaceutical companies can often block patient engagement activities, coupled with POs' limited understanding of the Code. Complex contracts are a significant barrier, as patients, carers, and POs often do not have access to legal advice.
- Early engagement leads to greater benefits, however the multiple entry points in pharmaceutical companies, complexity of global vs national engagement, internal communications, and POs capacity present barriers to this.

Recommendations

Companies and POs



Develop and support personal relationships



Build an understanding of each other



Develop overarching strategic frameworks

Companies



Engage with patients and POs earlier



Clearly communicate contact person



Improve standard operating procedures (SOPs) and infrastructure



Build on template contracts

Patient Organisations



Build an understanding of the Codes of Conduct



Develop your parameters for an effective partnership

Introduction and Scope

Patient engagement in research is well established in the UK. Over the last 20 years, government and charity-funded health research has increasingly been prioritised, designed and delivered in partnership with people living with health conditions, thus improving the relevance, quality and success of academic research[1,2,3,4]. Patient engagement in industry-led research is less well established but has gained significant momentum over the last 6-7 years, particularly with the establishment of initiatives such as Patient Focused Medicines Development (PFMD), and the EU funded Innovative Medicines Initiative project, PARADIGM, amongst others. Training, guidance, and patient engagement impact measures created through these programmes, has led to a greater understanding of the value of patient engagement. In particular, in designing and delivering research more efficiently and effectively, as well as increasing the role of patients in ensuring more meaningful outcome measures and improving regulatory and/or Health Technology Assessment (HTA) submissions. Because of this, pharmaceutical companies are increasingly seeking to work with POs.

POs are also becoming more open to working with pharmaceutical companies to ensure the needs and priorities of the people they work with can influence all aspects of research and medicine development. They are also interested in understanding companies' plans for their respective disease areas and gaining insights into development pipelines.

Versus Arthritis, a medical research and care charity in the UK, initiated this project because they wanted to understand more about how pharmaceutical companies are working with POs in the UK before developing their own plans to work with industry. As there were broader lessons and implications for this work, they invited several UK POs to form a steering group to advise on the direction of this project. Two people living with health conditions and two representatives from the pharmaceutical industry were also invited to join this group. Two freelance facilitators supported delivery of the project.

The project was funded by Versus Arthritis with contributions from Parkinson's UK and the Cystic Fibrosis Trust. The patient engagement company, MediPaCe, gave pro bono support for the literature review and the development, launch and analysis of the survey. This report has been written for POs that are interested in working with pharmaceutical and/or medtech companies, and for companies interested in developing relationships with patients, carers, family members and/or POs.

Initiatives

Patient Focused Medicines Development - https://patientfocusedmedicine.org/

Innovative Medicines Initiative PARADIGM – https://imi-paradigm.eu/

Methodology



Literature review

The first stage of this project was an informal literature review which included a search of published and grey literature for any relevant materials, reports, guidance documents, or publications related to:

1. POs (particularly in the UK but not excluding Europe) and pharmaceutical companies working together.
2. POs and pharmaceutical companies working together at different stages of the medicine development process.
3. Particular departments in pharmaceutical companies working with POs or vice versa.
4. Pharmaceutical companies needs with regards to patient engagement.

The review showed that there is a limited amount of information on how, when, and where in the medicines development process pharmaceutical companies are working with patients and POs. Instead, resources, articles, and reports focused on how companies aspire to work with patients and POs[5,6]; case studies[7-11]; or standards and best practice in working together[12-16]. There were also publications and guidance that outlined where companies and patients, carers and POs can, and should, be involved across the drug development process[17]. One recently published article was identified[18] that gave excellent

insight into different patient engagement types that take place at different stages of drug development process, with a focus on the degree of power patients have in the process. This review article mapped patient engagement activities that have been published in the literature, and then evaluated the depth and intensity of global patient engagement initiatives.

No literature available at the time of the review had mapped the current self-reported patient engagement activities of pharmaceutical and medtech companies working with patients, carers, family members and/or POs. Neither had the literature explored how pharmaceutical companies hope to approach patient engagement activities in the future or focused on the UK specifically.

This report is the first of its kind.

Survey

The survey aimed to gather information on:

1. The way in which pharmaceutical companies are currently engaging with UK patients, carers, family members and POs.
2. How pharmaceutical companies would like to do engage with UK patients, carers, family members and POs in the future.

The survey was launched in February 2022. It was shared with industry contacts by all members of the steering group, by other UK based POs who work with industry and was promoted by the Association of the British Pharmaceutical Industry (ABPI) by email and on social media. The survey remained open for 26 days.

Quantitative survey responses were analysed by a representative from MediPaCe, and qualitative responses were analysed by members of the steering group.

Workshop

The virtual workshop was planned and delivered by members of the steering group and held on 28th June 2022. The workshop participants were identified from survey respondents, who were asked to indicate if they would be interested in joining a virtual workshop to explore the survey results.

Thirty-seven people were brought together for the workshop to reflect on the results of the survey, and to discuss and prioritise areas of action that could help take relationships between pharmaceutical companies and POs in the UK from transactional to truly collaborative. The workshop attendees consisted of:

- Sixteen representatives from the pharmaceutical industry.
- Fourteen representatives from UK POs.
- Four people living with health conditions.
- Three additional people supported delivery of the workshop.

The survey results were sent to workshop participants in advance and the workshop included discussions and reflections on the survey results, as well as solution-focused discussions on ‘culture and building successful relationships’ and ‘collaboration and patient engagement throughout the medicines development process’. A copy of the workshop agenda is included in Appendix B.

Results

Survey results

There were 52 responses to the survey. Respondents overwhelmingly represented pharmaceutical and biotech companies (n=47), with a small number representing medtech companies (n=4) and a Contract Research Organisation (CRO). The top three therapeutic areas that companies specialised in included rare diseases (15%), oncology (13%), and neurology (10%) but a significant number of other conditions were also reported. Most respondents work in Corporate Affairs (12), Medical Affairs (11), Research & Development (9), Market Access (7) and Sales & Marketing (6). Most respondents had a local remit (i.e., their role covered the UK, n=29). Eight respondents had a regional remit (definition of this will vary between companies, for example 'Europe' or 'Benelux') and 13 were working globally.

Approach to patient engagement

Within companies, the functions that most frequently engage with patients, carers, family members and/or POs are Medical Affairs (22%), Research & Development (21%) and Corporate Affairs (17%) – see Figure 1.

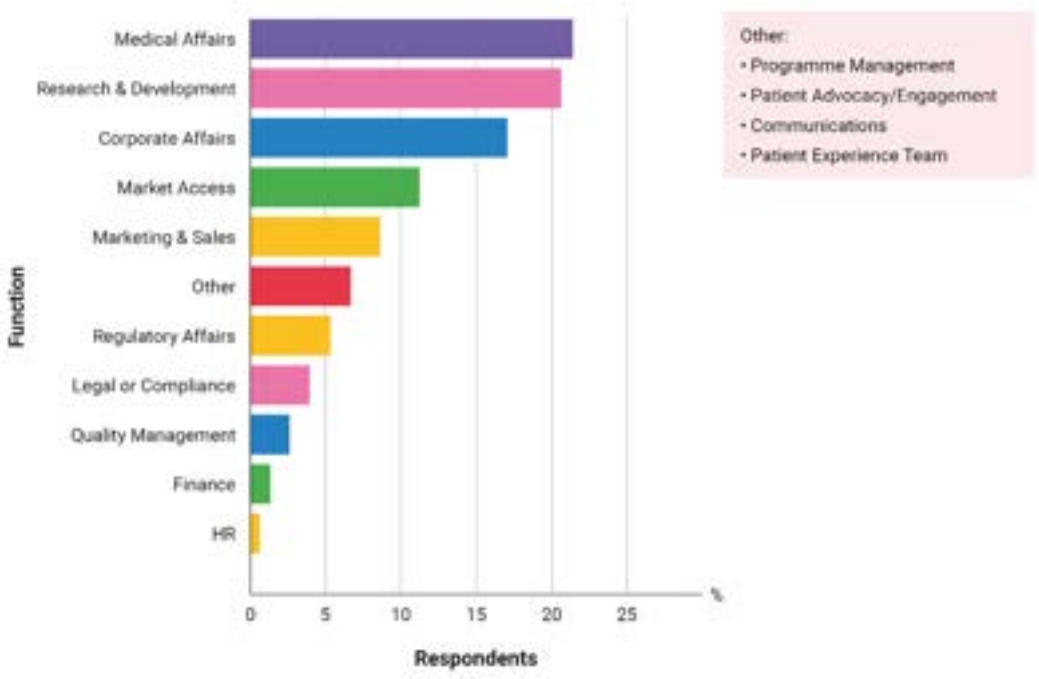


Figure 1. Which functions within your organisation currently work with patients, their carers and/or POs?

Value and impact of patient engagement

In response to a multiple-choice question about the value that is achieved from patient engagement, respondents most frequently selected:

- Better understanding of experience and unmet needs for more robust planning and programme delivery (n=45)
- Raise awareness and motivate staff members in your therapeutic areas (n=36)
- Informing and/or aligning on strategic aims and direction (n=34) – see figure 2.

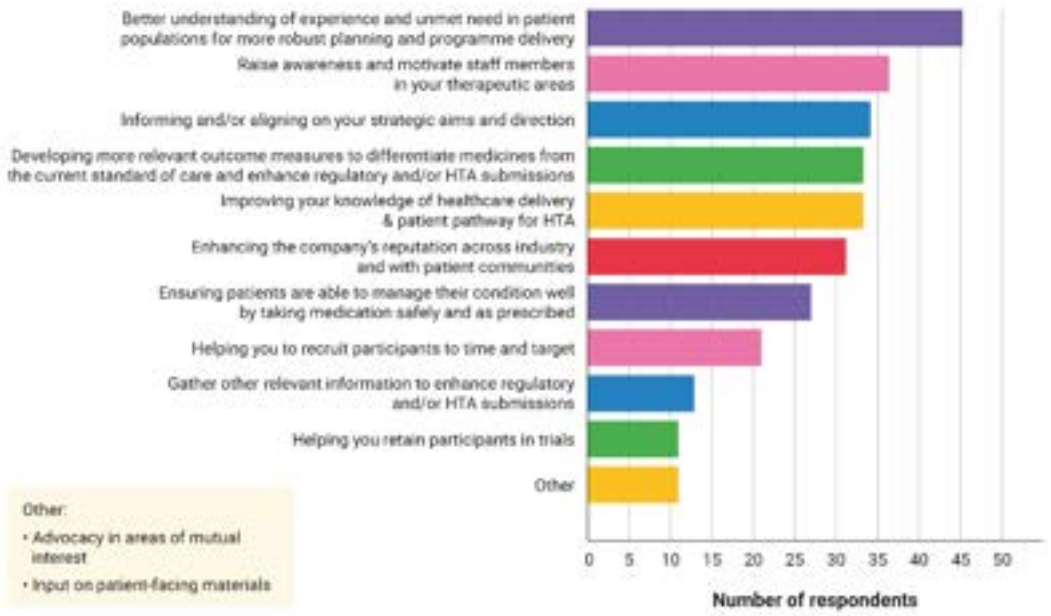


Figure 2. What value is achieved from your company's work with patients, their carers and/or POs?

However, when asked to select what is most important to the team/company, 'raising awareness and motivating staff members' was no longer among the most selected values. 'Improving knowledge of healthcare delivery & patient pathway for HTA' (n=16) and 'Developing more relevant outcome measures to enhance regulatory and HTA submissions' (n=16) rose to joint third – see Figure 3 and Table 1.

Value	**n**
Better understanding of experience and unmet need in patient populations for more robust planning and programme delivery	40
Informing and/or aligning on your strategic aims and direction	19
Improving your knowledge of healthcare delivery & patient pathway for Health Technology Assessment (HTA)	16
Developing more relevant outcome measures to differentiate medicines from the current standard of care and enhance regulatory and/or HTA submissions	16

Raise awareness and motivate staff members in your therapeutic areas	12
Ensuring patients are able to manage their condition well by taking medication safely and as prescribed (i.e. through Patient Support Programmes)	11
Enhancing the company's reputation across industry and with patient communities	10
Helping you to recruit participants to time and target	6
Other	4
Gather other relevant information to enhance regulatory and/or HTA submissions	3
Helping you retain participants in trials	2

Table 1. Which three values are most important to your team/company?

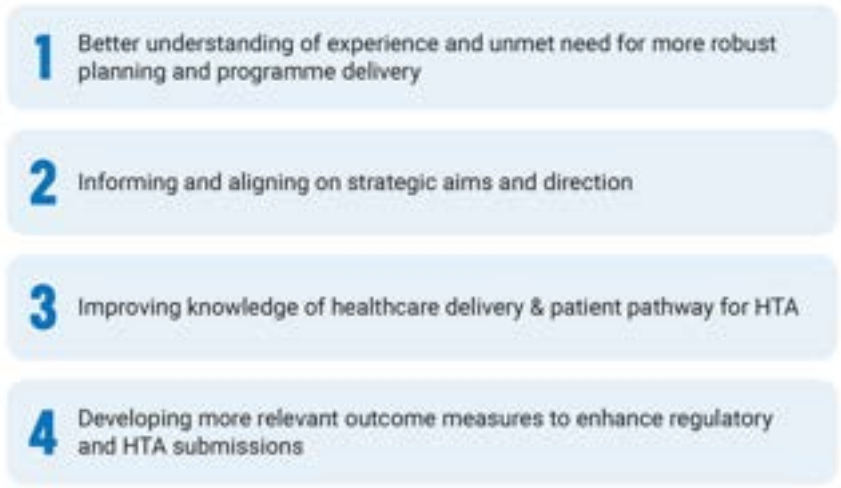


Figure 3. The value of patient engagement – three most important to teams/companies

When exploring the value of patient engagement, its impact and how much it influences the direction or decisions of companies, respondents reported that engaging with patients significantly impacts their work and significantly influences company decisions and direction when scoring on a scale of 0 (not at all) to 10 (significantly), see Figure 4.



Figure 4. Patient engagement: How much does it add value and impact and influence company direction

Respondents selected where across the medicines development process their teams (or company) are working with patients and/or POs (Figure 5). In a follow-up free text question respondents had the opportunity to describe how they are involving patients.

Unsurprisingly, most patient engagement is happening at the clinical research phase (n=38). The type of projects described included:

- Input on protocols (n=9)
- Activities driving recruitment and retention (n=8)
- Designing patient information materials and consent forms (n=7)

Thirty-three respondents reported conducting ‘post-marketing activity’. This included:

- Disease awareness campaigns (n=5)
- Patient experience/journey mapping (n=4)
- Patient support programmes (n=4)

Twenty-eight respondents indicated that patients had been involved in developing strategic aims for companies. Reported activities included:

- Understanding patient perspectives and identifying unmet needs (n=8)
- Setting/aligning priorities (n=7)
- Informing strategy (n=7)

The least amount of activity was reported at the safety review phase (n=8), preclinical research (n=13) and the regulatory review phase (n=14).

Understanding patient perspectives, experience and unmet needs were activities that were consistently observed across five stages of the medicines development process. Involvement in developing outcome measures and end points as well as inputting into protocols were common across three stages (Figure 5). Please note that respondents self-assigned their activities to the stages in the process.

Future of patient engagement

Sixty-four percent of respondents said they plan to increase their work with patients, carers, family members and/POs over the next two years. Respondents indicated they would like to increase their work at:

- the regulatory review stage (13%),
- the Health Technology Assessment (HTA) review stage (11%)
- in developing strategic aims (11%)
- at the discovery & development stage (9%).

Over 50% of respondents reported they are planning more projects to understand patient experience and needs. Other planned projects mentioned included involving patients earlier, particularly in Target Value Profile (TVP: a document companies produce very early in the product life cycle to understand the ‘value’ of the innovation to commissioners, governments, and the public) development, establishing frameworks to facilitate patient input into the planning process, and establishing patient panels to advise on activities.

The kind of relationship companies would like to have with patients and/or POs is also changing (see Figure 6). When commenting on current relationships, 8% of respondents reported having one-off relationships with patients, carers, and POs, 49% reported having established relationships, and 13% reported having long term relationships which involve co-creation.

Looking to the future, 6% would like to have one-off relationships, 18% established relationships and 76% would like to have long term relationships with co-created projects and plans. These results indicate a significant desire to move from transaction to collaboration.

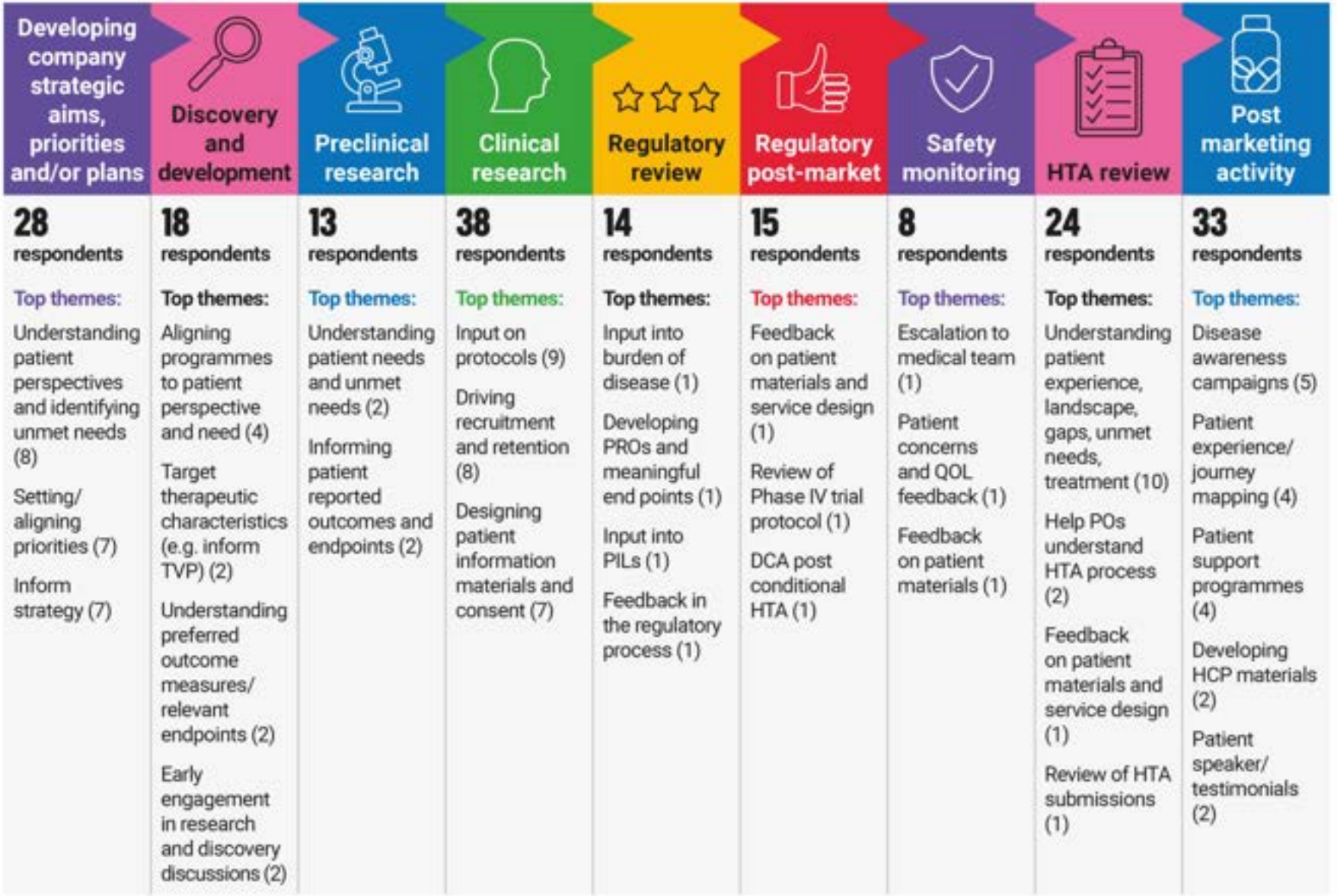


Figure 5. Patient engagement across the medicines development process and project themes

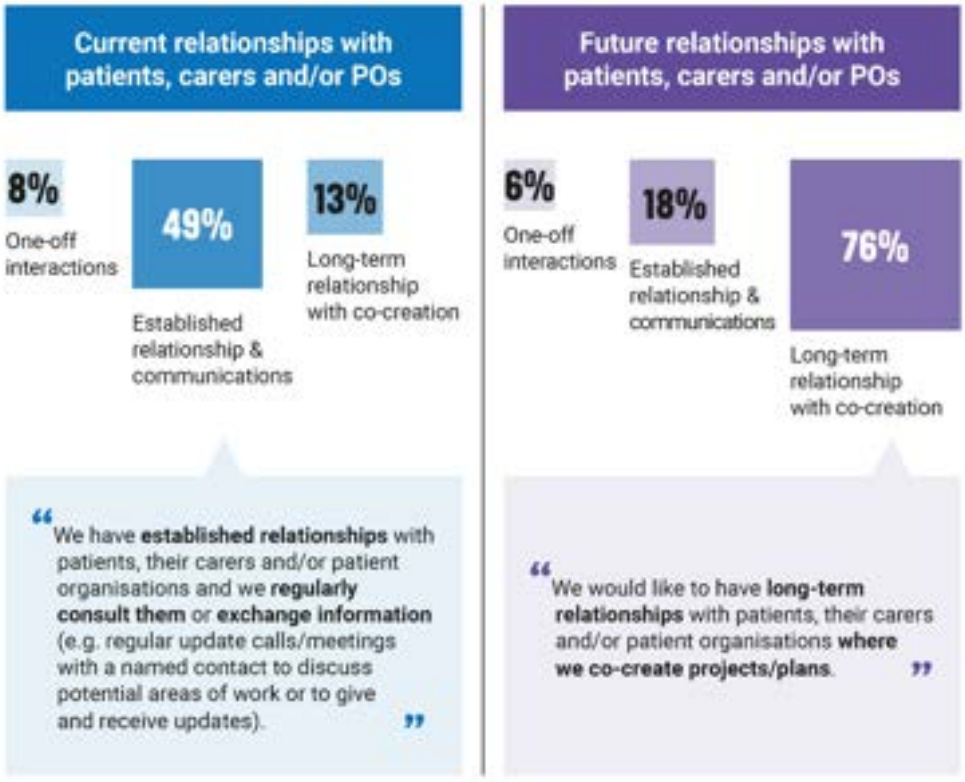


Figure 6. Current relationship vs future relationship with patients, carers, family members and/or PO

Working with POs

Finally, respondents said they felt that the role of POs in patient engagement activities was predominantly to sit alongside patients and carers and to contribute POs' perspectives to discussions and projects. This was followed by a role for POs in support to plan, manage and deliver engagement activities with pharma companies, see Figure 7.

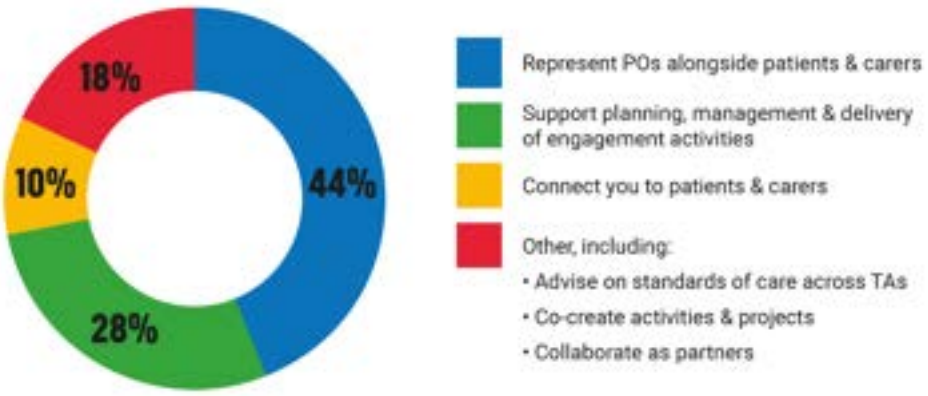


Figure 7. The role of POs in patient engagement activities

Workshop results

Reflections on the survey results

General reflections on the survey were positive with participants expressing their surprise at the range of different job functions responding to the survey.

Long-term strategic relationships

There was widespread consensus that the survey highlights the changing environment in which pharmaceutical companies and POs work together in the UK. Many participants noted that pharmaceutical companies want to work with POs earlier in the medicines development process, but also at a strategic level.

It was also noted that companies are moving from working on a project-by-project basis with patients and POs to longer-term engagement, where projects are co-created and co-delivered.

ABPI Code of Practice

In the UK, the ABPI Code of Practice governs how pharmaceutical companies can work with POs, individual patients, and the public.

Within pharmaceutical companies, legal and compliance processes are important and necessary, but varying interpretations and perceptions of risk in companies can often block patient engagement activities. For global activities, UK based POs can be excluded from meetings or not engaged at all.

Pharmaceutical company representatives reported that this was in response to the ABPI Code of Practice. The inconsistency in interpretation of the Code can also mean that POs are not able to apply their own understanding of the Code from one company to another and have little opportunity or power to question whether a company's interpretation is accurate.

Participants felt an increased level of understanding of the Code amongst POs would be helpful. ABPI representatives at the workshop commented that the ABPI Code aligns with other codes such as the European Federation of Pharmaceutical Industries and Associations (EFPIA), but that it has a higher level of enforcement in the UK. They agreed more clarity would help, including the sharing of best practice examples.

Initiatives

ABPI Code of Practice

Recruitment and retention in clinical trials

One participant from a PO shared that in a recent survey from their organisation, patients considering taking part in a clinical trial revealed that they want to be supported with both the physical and psychological aspects of the trial. Workshop participants from POs felt this was an area where POs could provide insight and practical support to pharmaceutical companies.

Another participant from a PO referenced that research has shown that involving patients in the design of clinical trials leads to better recruitment and retention. There was consensus from pharmaceutical representatives at the workshop that patients, carers, family members and POs have become more involved in designing clinical trials and protocols, but that this often happens at a global rather than a national level.

This was supported by our survey, where recruitment and retention were a lower priority in terms of value to the company when working with UK-based patients, carers, family members or POs.

Clinical trials are very often developed at a global level and teams based at country level are given a finished product in terms of trial design. Local UK teams are much more focused on post clinical trials, real-world evidence (RWE) generation, supporting HTA submissions, and ethnographic (the study of cultural patterns and perspectives) research.

Investment, changes in infrastructure and capturing impact

There was consensus that for engagement to happen, companies need to invest in advocacy resources within their organisation. Several pharmaceutical representatives felt that internal changes in SOPs and infrastructure would be needed to unlock more value from engagement, and that processes for capturing and sharing impact would be necessary to truly influence change.



Companies often ask consumers for feedback before launching a new product. Think of focus groups testing a new yogurt or tomato sauce. Consumer insights on texture or taste can lead to meaningful modifications. A clinical trial is similar – gaining stakeholder feedback early on can ensure the final trial design works for both patients and researchers.

That's where the Pfizer Protocol Optimization team comes in – a global centralized group that gives study teams the opportunity to pressure-test their designs with feedback from patients and carers. Protocol Optimization brings together multiple methods used to simplify clinical trial protocols and test assumptions, these include engaging with and obtaining patient insights.

Thanks to the team's efforts, every study team can use one or more of these methods to gain feedback on study methodology, helping to avoid protocol amendments later that can increase timelines and costs as well as retention of participants.

Examples of modifications are when Patient Insights have led to changes in patient-facing materials or a reduction in the frequency of certain procedures like blood draws. The team begin looking to engage with patients as soon as possible when the protocol is in the very early stages of development so there is time to incorporate patient feedback into the design of the protocol. If, in the rare instance, the protocol has had to be finalised before patient insights have been obtained, patient feedback is still gleaned as this can influence the training of site staff, the design of the recruitment material or subsequent protocol amendments.

Elements of protocol optimization, such as Patient Insights, are now requirements for designing a clinical trial at Pfizer. As a Global Pharmaceutical company, it can be challenging to ensure that Global studies include local country input.

In Pfizer we see the importance of including perspectives from across the world and, in order to do this, the Pfizer Protocol Optimization team has worked with the various bodies including the National Institute of Health Research (NIHR) Patient Engagement Service and POs to ensure UK patients' and carers' perspectives are included.

Breakout discussion results

Breakout discussions focused on two main areas: Culture & building successful relationships between industry and POs; Collaboration & patient engagement across medicines development.

Culture & building successful relationships between industry and POs.

There was acknowledgment that there is still disparity in the perceived value and influence of patient engagement, perhaps because of the competing demands with other influences such as scientific rigor and business priorities. More needs to be done internally within companies to embed patient engagement into the culture and support consistent prioritisation.

Complex contracts are still a significant barrier when engaging with patient, carers, family members and POs. Participants reflected that often patients, carers, and POs, especially those without easy access to legal advice, are signing documents that they do not understand. A representative from a pharmaceutical company reflected that the complexity of contracts relies on a legal expert to help interpret. In their experience, even "*the medical teams executing the contract often do not understand the contents of the contract – only the legal team does*". Contracts written in plain language, or contracts with lay–friendly sections are something that should be considered by companies serious about collaboration and creating a safe environment. POs could consider asking for this, or for a contact person to answer queries on the contract in the initial stages of setting up projects.

The importance of personal relationships with a key contact on both sides, and regular communication, were clearly observed in the survey results. This was reinforced by discussions at the workshop as essential for successful collaboration, both from POs and industry representatives. In the workshop, some PO representatives spoke of the frustration when a personal relationship has been built, but a contact is lost due to staff changing jobs. Often, POs are not told who the new person in role is, or there is no replacement. Even if someone does come into the position, it is probable that there has been no handover so rebuilding the relationship is challenging, if it happens at all. Having processes in place to ensure 'organisational memory' were considered key for building and maintaining successful, lasting relationships. Setting out these expectations and processes at the beginning of the working relationship can help. Having two people from each organisation involved in meetings was also suggested as a possibility for ensuring continuity if a member of staff from either side should move on.

One PO suggested putting in place an overarching strategic agreement template which sets out why and how a PO and a pharma company will work together, expectations on both sides, as well as processes to follow in different circumstances. With this overarching agreement is in place, different areas and departments of both organisations can work together and it avoids both parties repeating the complex, time consuming contractual process. It also offers reassurance to departments or personnel who might be nervous about engaging with POs or less familiar with patient engagement, as an agreement is already in place, allowing for more creative conversations and ideas. Finally, this arrangement also offers safety and protection, a standard of working to both the PO and the company, and establishes a long term, meaningful, equal collaboration.

Prostate Cancer Research uses a collaborative framework agreement when working with industry. Jayne Spink, Director of Translational Research, reflects on why companies and POs might consider establishing such an agreement before working together and outlines key considerations.

When a company and a third sector organisation consider that they may wish to collaborate to deliver more than one project sequentially or concurrently, and/or work with multiple teams or departments, it may be helpful to consider establishing a framework to govern their respective rights and obligations. An agreement setting out the terms and conditions of collaboration, upon which the parties have agreed, can serve to:

- Provide clarity as to the nature of the relationship
- Speed up progress of proposals
- Provide for the bulk of contractual documentation allowing parties to focus on the detail of project agreements by way of a template schedule
- Support long-term relationship management and improvement
- Support agreement on, and delivery of, collaborative projects

Such a framework agreement should outline the circumstances under which collaborative projects might be proposed by either party. It should also set out how such proposals will be considered and discussed, with an acknowledgement that either party is entitled to decline to agree to formalise a proposal into a project.

What should be considered in the framework agreement?

The overarching framework agreement should:

- Set out the range of **activities** envisaged, i.e., the ways in which the parties might utilise their specific resources and expertise to deliver benefits for patients. This might include, for example, protocol review, diversity and inclusion support, advisory board support, co-development of awareness campaigns and social research projects.
- Make clear the position in relation to **Intellectual Property Rights**, whether registered or unregistered.
- Stipulate the **commencement date** of the framework agreement, the continuation period and the provisions for earlier **termination** that will apply.

- Describe how the framework agreement will be **monitored**, including frequency of meetings, the setting of agendas, arrangements for minuting, circulation and approval of minutes.
- Arrangements for any transfer of funds, including invoicing and payment where appropriate and aligned with project schedules.
- Set out the **responsibilities and obligations** of:
    - the patient organisation (including provision for annual reports if applicable)
    - the company
- These obligations should include detailed provisions for use of name and logo of either party. The nature and arrangements relating to external communications should be documented.

What additional considerations should be taken into account?

The framework agreement should contain clauses relating to:

- Confidentiality and disclosure
- Compliance with data protection legislation
- Compliance with policies and codes
- Anti-bribery
- Indemnity and limitations / exclusions of liability
- Insurance in relation to range of activities to be potentially undertaken
- Grounds for termination and obligations (under project schedules) that apply where a project is terminated.

What provision should be included in relation to individual proposals and projects?

The project schedule should include a template for project proposals, designed to meet the needs of the relationship. Such templates may include space to set out deliverables, milestones, budget, and so on. If both parties agree and sign the project schedule, it becomes part of the framework agreement rather than requiring the issuing and signing of an entirely de novo contract for the project (the framework agreement being integral to the project contract).

Capacity, communication, and infrastructure – getting ready for collaboration isn't easy!

The earlier that pharmaceutical companies and POs engage with each other in the process of medicines development, the greater the benefits for the company, PO and ultimately for people living with health conditions. However, workshop participants noted that there are many barriers to this taking place. These include:

- The breadth of possible entry points to engagement (different departments across the company with different remits and priorities)
- The added complexity of global vs national engagement
- Internal communication (the most significant relationships are often built at national level and global colleagues do not always communicate with local teams)
- Where companies are in their life cycle
- Whether a PO wants or has the capacity to engage.

These barriers mean that engagement is not a simple process. Putting infrastructure and processes in place to ensure early, streamlined, meaningful engagement is a significant task for companies, particularly larger ones.

Similarly, it's important to recognise that POs are not a one-size-fits-all partner. Some POs have processes in place and a small number will have legal teams that can support them to engage with pharmaceutical companies with confidence, and the ability to advocate for themselves in the relationship. Others very often lack this experience, resource, and infrastructure. Larger POs may have established programmes that enable them to be an equal collaborator and act as facilitator, whilst smaller charities just do not have the capacity for this kind of relationship. Whilst they may not have significant capacity, this does not negate how significant and beneficial collaboration can be.

Understanding potential internal issues and challenges, how both parties want to engage with the other and what is needed to enable a successful collaboration, is an important piece of work for both companies and POs.

Understanding how companies and POs work differently.

Understanding and respecting each other's challenges, as well as the significant potential in collaborating, goes a long way to starting to build the foundation for those relationships.

The importance of a better understanding of how each other works was evident in the survey. Companies wanted POs to understand constraints that they face about the industry's codes of practice and how they are allowed to communicate with the public. POs in the workshop also felt it would be helpful for companies to develop a clearer understanding of POs, particularly the limited resources to deliver activities in smaller organisations and the importance of fundraising activities. This point was echoed across all discussions and breakout sessions.

Co-creating from the start.

POs said that they often do not know which companies are working in their disease area, or what stage of medicines development they are at. This means that there is often no advanced warning that they will be approached to engage, and they are forced to be responsive, rather than proactive in working with companies.

POs also reported that they rarely come across a company that has thought ahead and entered a strategic relationship early, despite all participants agreeing that engagement is best early and in the pre-competitive space. The perception that POs are most often seen as useful for HTA, and market access, is problematic for trust and relationship building. POs do not like to be engaged with late on in the process, seemingly for the purpose of gaining regulatory approval and ultimately profit. By this point, it's too late to incorporate patient perspectives and needs into programmes by, for example, measuring what is important to patients in trials.

In addition, often engagement is on a project-by-project basis and, as such, are planned and delivered without strategic oversight There should be more of a long term, portfolio approach, involving more senior members from across the organisations, especially while establishing the relationship and agreeing areas of mutual benefit and shared goals. Projects can then be delivered under this overarching strategic plan/agreement. This could help avoid relationships from feeling transactional.

What is the PO role?

We have already noted that POs are different sizes, have different resources, structures, capabilities, and priorities. There are different roles POs can have when collaborating with companies. These include:

- Facilitating access to patients

- Sitting alongside patients to offer support and to offer a range of perspectives
- Working with pharma companies to plan and deliver projects or activities to gain insight from patients
- Providing a service to the company by taking responsibility for the delivery and reporting of the project
- Collecting and sharing either existing or newly generated patient data
- Offering objective expert knowledge of the disease and wider community.

Whatever it is, this role should be well defined at the start of the collaboration. The cost of the PO's time must be appreciated fully. Even responding to emails from a company can take up a significant amount of time. Smaller charities are often not able to bear this cost.

Having a balance of PO representatives, patients, carers and family members in any patient engagement activity on advisory boards and steering groups within projects is important, because having the PO's perspective does not always mean the patient's perspective is included. Patients and POs can bring unique and different perspectives.

In the UK, patient involvement and engagement culture and practices are well established across health research. There is a significant number of POs in the UK already supporting the research community to work with people affected by health conditions. Pharmaceutical companies may not be aware of these programmes and the potential to work with POs and people living with health conditions through these programmes. Pharmaceutical representatives expressed that it would be useful to understand the opportunities to work with UK based POs, particularly when they set up a new trial or operate in a new therapy area.

It is important to also remember that not all POs have the capacity to support patient engagement and involvement activities. If they do, they may not be open to working with companies in this way, due to organisational policies or potentially the preference of their communities.

Conclusions

This was the first project of its kind and clearly demonstrates that patient engagement is happening across the medicines development process. Whilst this is mostly happening at the clinical trial phase and post-marketing authorisation process, there is activity at an early stage. There is significant interest from companies in working with patients, carers, family members and Patient Organisations, to understand patient perspectives, experience, and unmet needs, develop outcome measures and end points, as well as gaining input into protocols.

Patient engagement is also considered important, valued, and impactful by teams and companies. There is a strong desire from companies to move to a more collaborative approach to working with patients, carers, family members and POs earlier in the medicines development process, and in developing company strategic aims and direction.

Significant barriers to patient engagement still do exist though. Meaningful patient engagement from the start is not a simple process. Increasing our understanding of each other and developing strong relationships, with key contact people from the start, is essential.

This project has developed several recommendations for Patient Organisations and industry as sectors to consider. Individual recommendations that can be implemented at an organisational or company level have also been proposed.

We would like to invite those acting on some, or all, of the recommendations in this report to please share this with us by emailing.

Thank you once again to everyone involved in this project.

Recommendations

Based on these discussions, the steering group for this project has developed the following recommendations for action.

For pharmaceutical companies and Patient Organisations:

- Develop and support personal relationships between more than one member of staff in each organisation, to protect organisational memory and the ability to continue to deliver the work.
- Develop overarching strategic agreements about how companies and Patient Organisations will work together as a framework beneath which specific projects can be delivered with a long-term intent and vision.

For the UK Patient Organisation sector:

- Build an increased understanding of the ABPI Code of Conduct, which governs how pharmaceutical companies interact with patients and Patient Organisations.
- Build an understanding of how pharmaceutical companies work and the roles of different departments.

For individual Patient Organisations:

- Build an understanding of the companies in your disease/charity focused area and invite them to connect, to understand if they have shared goals and a willingness to collaborate.
- Develop a check list of what is required for an effective partnership when working with companies from your organisation's perspective. If possible, work with your key partners to do this.

For pharmaceutical companies:

- Build an understanding of how Patient Organisations work and support them to understand how you work.
- Engage with patients and Patient Organisations as early as possible in the medicine's development process.
- Clearly communicate (on website) who Patient Organisations can contact within your organisation to discuss potential collaborations.
- Work to embed working in partnership with Patient Organisations as the norm across your organisation and culture.
- Explore standard operating procedures (SOPs) and infrastructure to consider if there are aspects that can be improved to support engagement with patients and Patient Organisations, and to capture the impact of this.
- Further build on template contracts developed by WECAN, by ensuring contracts are either written in plain English, or that they are accompanied by plain English explanations of the legal text.

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Appendices

Appendix A: steering group members

Angela Davies, Versus Arthritis

Rachel Peters, Versus Arthritis

Caroline Aylott, Versus Arthritis

Anne Channevy, Versus Arthritis Research Partner

Nikul Bakshi, Parkinson's UK

Lorna Allen, Cystic Fibrosis Trust,

Marie Ennis O'Connor, Patient Advocate & Health Communications Expert

Julie Clayton, Alopecia UK

Anna-Louise Smith, Alzheimer's Society

Samantha Barber, Gene People

Annee Amjad, MS Society

Krisnah Poinasamy, Asthma & Lung UK

Victoria Bates, Association of the British Pharmaceutical Industry

Sally-Anne Dews, Pfizer

Charlotte Hooker, MediPaCe (and additional freelance support)

Freelance support for the project:

Claire Nolan, Project Manager

Bec Hanley, Steering Group & Project Facilitator

Appendix B: virtual workshop agenda

From transactional to truly collaborative: Exploring new ways of working between the pharmaceutical industry and UK-based patient organisations

Tuesday 28th June 2022 - 13:00-16:00 BST

Zoom Link: https://us02web.zoom.us/j/86208151709

Time	Session	
13:00-13:20	**Welcome, plan for time together and introductions**	
13:20-13:55	**Presentation of survey results followed by Q&A**	
13:55-14:30	**BREAKOUT SESSION 1**	
	Group A & B - Culture and building a successful working relationship **Discussing:** • *Successful long-term relationships* • *Opportunities to meet and understand each other* • *Role of all stakeholders including patient organisations themselves in developing successful relationships*	**Group C & D - Collaboration & patient engagement right across the medicines development process** **Discussing:** • *The role of patient organisations in facilitating/supporting patient engagement activities* • *How to embed working together right across the medicines development process and beyond?* • *Partnering on meaningful activities*
15 mins	**BREAK**	
14:45-15:20	**BREAKOUT SESSION 2**	
	Group C & D - Culture and building a successful working relationship *(Discussions outlined above)*	**Group A & B - Collaboration & patient engagement right across the medicines development process** *(Discussions outlined above)*
15 mins	**BREAK**	
15:35-16:00	**Plenary session - priority setting and next steps**	
Total 3hrs	**CLOSE**	