BMJ Open

Characterising meaningful patient and public involvement in the pharmaceutical industry research setting: a retrospective quality assessment

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To cite: Dews S-A, Bassi A, Buckland S, *et al*. Characterising meaningful patient and public involvement in the pharmaceutical industry research setting: a retrospective quality assessment. *BMJ Open* 2023;**13**:e071339. doi:10.1136/bmjopen-2022-071339

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-071339).

Received 04 January 2023
Accepted 14 July 2023

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ABSTRACT

Objectives Patient and public involvement (PPI) in clinical research has a well-established infrastructure in the UK, and while there has been good progress within pharmaceutical-industry-sponsored research, further improvements are still needed. This review aims to share learnings from quality assessments of historical PPI projects within Pfizer UK to inform future projects and drive PPI progress in the pharmaceutical industry.

Design and setting Internal assessments of Pfizer UK PPI projects were conducted to identify all relevant projects across the medicines development continuum between 2017 and 2021. Five sample projects were developed into case studies.

Outcome measure Retrospective quality assessments were performed using the Patient Focused Medicines Development (PFMD) Patient Engagement Quality Guidance (PEQG) tool. Recommendations for improvement were developed.

Results Retrospective case study analysis and quality framework assessment revealed benefits of PPI to both Pfizer UK and to external partners, as well as challenges and learnings to improve future practice. Recommendations for improvement based on these findings focused on processes and procedures for PPI, group dynamics and diversity for PPI activities, sharing of expertise, the importance of bidirectional and timely feedback, and the use of understandable language in materials.

Conclusions PPI in medicines development is impactful and beneficial but is still being optimised in the pharmaceutical industry. Using the PFMD PEQG tool to define gaps, share learnings and devise recommendations for improvement helps to ensure that PPI is genuine and empowering, rather than tokenistic. Ultimately, these recommendations should be acted on to further embed PPI as an integral part of medicines development and health research within the pharmaceutical industry. This article includes a plain language summary in the supplement.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This qualitative assessment was carried out against an established and validated framework, the Patient Focused Medicines Development Patient Engagement Quality Guidance tool.
⇒ The collaboration of pharmaceutical company employees and external partners with expertise in the field of patient and public involvement and lived experience who were brought together for the conduct of this review represented a heterogeneous and diverse range of perspectives.
⇒ The external partners may not be representative of the wider public, and their selection from a wider pool of potential partners may have resulted in the omission of some perspectives.
⇒ This retrospective qualitative assessment relied on the provision of historical evaluations and is subject to recall bias.
⇒ This work was conducted by the UK division of a single pharmaceutical company and their external partners; therefore the findings may not be fully representative of cross-industry or global perspectives.

INTRODUCTION

Patient and public involvement in health research

Patient and public involvement (PPI), also known as PPIE to incorporate engagement, is an initiative to include patients, family members, carers and members of the public in the research process of developing and improving health services and medicines.[1 2] It may be both democratic, to enable the inclusion of voices on the basis of principle, and instrumental, to drive change and improvement according to the needs of users. There are many terms used to describe PPI interactions, which are often used interchangeably. These include involvement, engagement,

consultation and participation. The definitions used for the purposes of this research are as follows.

1. *Involvement:* when research is 'carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them'. It is an active collaboration between patients, public and researchers.[2]
2. *Engagement:* when research information is shared with the public, for example, at research open days or on social media. Engagement is a two-way process, involving interaction and listening, with the goal of generating mutual benefits.[2–4]
3. *Consultation:* when feedback and input are solicited from people on how research or other PPI activities are carried out.[5]
4. *Participation:* when people take part in research, ranging from a one-off survey or questionnaire completion to recruitment into clinical trials or research studies for the active testing of experimental medicines and procedures.[2]

This paper focuses on PPI with patients and carers as external partners, also known as lay contributors or experts by experience, in the activities of a pharmaceutical company relating to medicines development, rather than as subjects of research.

The UK has a well-established infrastructure to enable meaningful PPI, backed by government policy, regulations and research funders.[6–11] The 'gold standard' model of PPI is based on both scope and depth of involvement; individuals should be contributing early on in research processes from strategy and governance with contributions to generating research ideas and priority setting, through to delivery and reporting of research, but also ensuring that PPI contributions are meaningful and of high quality regardless of the research stage. PPI in research has grown markedly in importance;[12–14] it is integral to the conduct of academic research and service redesign in the UK and is often mandated by funders such as the National Institute for Health and Care Research (NIHR).[15] However, the following questions remain pertaining to PPI in pharmaceutical industry-led research and projects.

- Is the development of a PPI infrastructure and meaningful involvement reflected within the pharmaceutical industry?
- What is meant by meaningful PPI?
- Why should PPI be important to the pharmaceutical industry?
- What is the importance of PPI opportunities to patients and carers?

PPI in medicines development: a Pfizer perspective

According to the Association of the British Pharmaceutical Industry, the goal of pharmaceutical companies is to bring the right treatment to the right patient at the right time.[16] The pharmaceutical industry increasingly recognises that research strategies and products must be built based on what matters to patients, or companies will cease to have purpose. Pharmaceutical companies are also recognising the value of PPI and are increasingly including and expanding PPI practices across the medicines development continuum, to ensure that research is truly focused on the needs of future users.[17] Opportunities exist to implement end-to-end collaboration from study development and design—by capturing outcomes and values relevant to patients—through to dissemination of outputs and development of educational materials and policy. True partnership includes genuine dialogue and a feedback loop with all involved.

Leveraging their long-term partnership with the NIHR, Pfizer, like many innovative pharmaceutical companies, has involved patients and carers in clinical development programmes[18] and continues to expand PPI practices across the medicines development continuum and earlier on in individual programme development. However, there are still barriers to becoming truly patient-centric, particularly for global companies in which organisational decision-making can sometimes be a challenge and/or feel very remote from patients, particularly for those operating in geographical regions where PPI is less well established. This is in part due to the differing compliance requirements across countries, a variable recognition of the benefits and impact of PPI and, sometimes, a lack of knowledge and operational expertise. There is also a need to manage shareholder expectations and the concrete manifestations these expectations create in terms of timelines and the ability to gain input from all external stakeholders; pharmaceutical companies are profit-making organisations, but they are increasingly defining themselves as purpose-driven. These industry-wide organisational challenges demonstrate the importance of undertaking and sharing PPI quality assessments and the relative novelty of doing so, both for democratic reasons to align with purpose-driven organisational goals and for instrumental reasons to ensure that medicines are fit for purpose.[19 20] Ultimately, changing company culture to create an environment in which employees are compliantly and systematically involving patients and external partners is the first step, but maintaining meaningful, high-quality PPI is the goal.[21]

Guidelines and frameworks to enable meaningful PPI

There are several UK guidelines, frameworks and governances in place to facilitate and guide the integration and reporting of meaningful PPI in health research.[22–26] Given the growing focus on meaningful PPI within pharmaceutical medicines development, there have been recent initiatives to develop frameworks specifically for the pharmaceutical industry.[27–29]

Within Pfizer UK, the Patient Focused Medicines Development (PFMD) Patient Engagement Quality Guidance (PEQG) tool[30] has emerged as a standard internal benchmark for PPI work for self-reflection and to recommend future ways of working. The preference for the PEQG tool is based on the robust process that went into designing it, specifically with medicines development in mind. It is a practical, easy-to-use guide that was co-created by the

multistakeholder PFMD collaboration, of which Pfizer is a partner, that involves industry, academia and patient organisations. The tool can be used prospectively or retrospectively to plan, develop and assess the quality of PPI activities and projects throughout medicines development.[29 31] There are four key stages of the tool: (1) basic information, (2) quality assessment, (3) results and outcomes and (4) lessons learnt. The quality assessment stage considers seven key quality criteria: (1) shared purpose, (2) respect and accessibility, (3) representativeness of stakeholders, (4) roles and responsibilities, (5) capacity and capability for engagement, (6) transparency in communication and documentation and (7) continuity and sustainability.

PPI in pharmaceutical medicines development in the literature

Prior to undertaking the current retrospective quality assessment, an initial scoping review of the MEDLINE and Embase databases was performed via Ovid to contextualise the current landscape of reporting on PPI initiatives in pharmaceutical medicines development in the literature. Publications reporting on PPI in medicines development from database start dates to October 2021 were identified using the search terms, 'pharmaceutical industry', 'medicines development', 'drug development', 'patient engagement/involvement', 'carers', 'patient centricity' and relevant synonyms (online supplemental appendix 2). The initial search yielded 157 papers. There was an increase in publications over time, with 54 records (34.4%) having been published between 1970 and 2015, and 103 records (65.6%) published between 2015 and 2021, demonstrating the recent increase in the importance of, and emphasis on, PPI. Approximately half of the publications (n=76 [48.4%]) were specific to medicines development, but few (n=32 [20.4%]) were published by the pharmaceutical industry, confirming a gap in reporting on PPI in pharmaceutical medicines development.

Current aims and objectives

Pfizer UK is adopting a strategic and meaningful approach to PPI across medicines development by reflecting on practices, with the goal of sharing learnings with the wider community and presenting recommendations for future improvement, particularly in light of the limited literature on the topic. This assessment was a collaboration between Pfizer colleagues and non-pharmaceutical partners, including patients, carers, patient organisation representatives and NIHR and National Cancer Research Institute representatives, all of whom have previously been involved in Pfizer PPI projects. Here, we aim to consider the following.

- What PPI has Pfizer conducted across medicines development in the UK in the past 5 years?
- How has Pfizer partnered with patients and carers and what were the benefits to both parties?
- What does meaningful quality involvement look like, based on the PFMD PEQG tool?
- What were the challenges, lessons learnt and recommendations to drive future improvements?

METHODS

Statement of PPI and formation of the manuscript writing group

A multistakeholder group including Pfizer employees and external partners was established from the outset for project review, case study development, quality assessment and manuscript development. Pfizer employees (n=7) were from the following departments: Medical Affairs (n=4; SB, SH, BP and NB), Medical Patient Partnerships (n=2; S-AD and LC) and Global Product Development (n=1; SE). External partners (n=7) had previously worked with Pfizer on PPI in medicines development and have PPI expertise and/or lived experience. This included a young person (n=1; AB), a carer (n=1; RD), an adult patient (n=1; KS), an NIHR representative (n=1; GP) and patient organisation or advocacy group representatives (n=3; AD, JP and EK). All external partners were involved in the design and conduct of the review, selected outcomes measures and contributed to the development of this manuscript, in line with the International Committee of Journal Medical Editors authorship criteria.[32]

Sample project identification, retrospective quality review and external validation

An internal assessment of Pfizer UK PPI projects was conducted to identify all projects undertaken across the medicines development lifecycle in the last 5 years before project commencement, from 2017 to 2021. Samples of these projects were chosen for assessment against the PFMD PEQG tool and written up into case studies according to a predefined proforma. Selection criteria for sample projects ensured that they represented different stages of medicines development across different years in the 5-year duration and that they had writing group individuals involved. The rationale for this was that writing group members would have a first-hand understanding of their projects and relevant connections for external feedback and were therefore best placed to evaluate the case studies. The PFMD PEQG tool was selected for assessment on the basis that it was designed specifically for medicines development, codeveloped with a multistakeholder group, has been used previously within Pfizer and is considered user-friendly and easy to apply.[29]

Sample projects were retrospectively assessed using the PFMD PEQG tool to identify gaps and draw out benefits and challenges, as well as learnings and recommendations for future practice. For external validity and accuracy and to allow a wider perspective on specific areas of development, the case studies were reviewed by up to three individuals each who were external to the writing group but who had been involved in each of the respective projects, except for one case study for which finding such an individual was not possible. These individuals included 11 external partners (patients, carers, young people and patient organisation representatives) and three Pfizer employees who were all asked to evaluate the

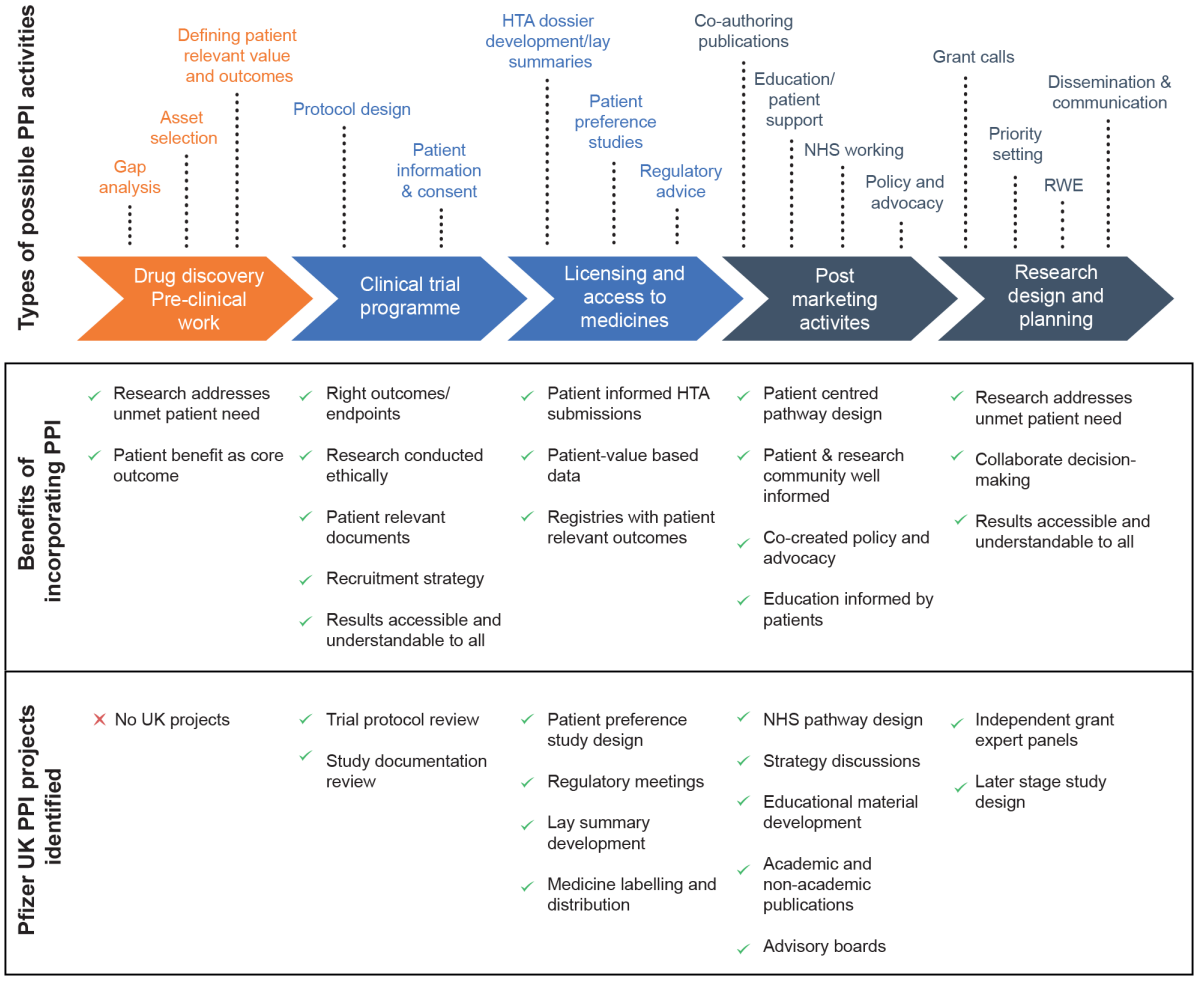

Figure 1 Types of possible PPI activities, the benefits of incorporating them and the Pfizer UK PPI projects identified across the medicines development continuum. HTA, health technology assessment; NHS, National Health Service; PPI, patient and public involvement; RWE, real-world evidence.

case studies against predefined questions (online supplemental appendix 3). Discussion and consensus of challenges and lessons learnt among the writing group led to establishing the final gaps and recommendations for future best practice.

RESULTS

Project identification

Overall, approximately 50 Pfizer projects were initially identified in which UK patients, carers or patient organisations were involved along the medicines development continuum over the past 5 years from 2017 to 2021. The level and type of involvement differed depending on the stage of medicines development (figure 1). Otherwise, there was a fairly even distribution of projects, with varying levels of involvement, across medicines development. Most involvement was identified at the clinical trial stage, within clinical development programmes (n=15). In contrast, few UK projects were identified at the drug discovery stage, with minimal involvement during the generation of real-world data and evidence and during post-authorisation activities. Five sample projects were selected to be analysed in more detail and written into case studies (online supplemental appendices 4–8).

Retrospective assessment using the PFMD PEQG tool

Stage 1: basic information

Selected sample projects ranged from early phase clinical trials to post-authorisation independent competitive grant programmes. All sample projects were completed in a single year within the 5-year period, included a range of stakeholders and represented a combination of established groups and newly formed groups (table 1).

Stage 2: quality assessment

Sample projects were systematically and retrospectively compared against the seven PFMD quality criteria to assess quality of involvement and to identify gaps for future improvement. Table 2 provides an overview of each quality criteria assessment and the gaps identified.

Stage 3: results and outcomes

Collated feedback showed that benefits and challenges of PPI varied depending on the project (table 3), but bidirectional sharing of learnings was important across

Table 1 Basic information of the five sample projects

Project title	Type of engagement (number of meetings)	External collaborator	Individuals involved	New or established group	Stage of medicines development	Year of completion
Working with patients to review a rheumatology clinical trial protocol	Face-to-face (1)	Versus Arthritis	Nine adult patients	Established, but not all had worked together previously	Phase 4 clinical trial	2017
Working with young people to review a dermatology clinical trial	Face-to-face (1)	GenerationR Liverpool YPAG	Nine young people	Established	Phase 1–3 clinical trial	2018
Working with an NIHR patient focus group to review two gastroenterology clinical trials	Face-to-face (1)	NIHR Clinical Research Network	Five adult patients	New group	Phase 1–3 clinical trial	2019
Working with parents and carers to review dermatology study documentation	Virtual (2)	GenerationR Liverpool Parent/caregiver focus group	Seven parents and carers	Established	Phase 1–3 clinical trial	2020
Independent medical grant call: quality improvements in rheumatology practice: delivering change for patients	Virtual (5)	Versus Arthritis and NHS clinicians	Two clinicians, two adult patients, one carer and one patient organisation representative	New group	Awarding independent medical grant(s)	2021

NHS, National Health Service; NIHR, National Institute for Health and Care Research; YPAG, Young Persons' Advisory Group.

all projects. For Pfizer, key learnings helped to change clinical trial protocols and associated documentation, to improve understanding of priorities and to ensure research is patient-focused. For patients and carers, there was benefit in understanding the workings of a large pharmaceutical company and how their feedback can lead to change, and in having the opportunity to have their opinions heard and feel listened to. Reported challenges included time taken to set up projects, timings of meetings and ensuring materials were truly lay-friendly.

Stage 4: lessons learnt and external validity check

Lessons learnt captured by the writing group and added to during the external validity check are included in table 4. The additional external validity assessments collected quality assessment feedback from individuals who were part of the individual project groups, but not included in the manuscript writing group; this was collected for four out of five projects and documented in the case study reports. This was not possible for the NIHR Gastroenterology project owing to a lack of availability of project group members. In general, the individuals that gave feedback felt that the case studies were an accurate representation of the projects they were involved with.

Development of recommendations

Based on the findings from the assessment using the PFMD PEQG tool, defined gaps and lessons learnt, a set of recommendations were established to improve PPI. These are grouped based on the seven quality criteria and will form the basis of an action improvement plan within Pfizer.

1. Shared purpose

- Time is required at the start of a project, to define a shared purpose that is agreed on by the group, written down and revisited at each meeting, and adjusted if the purpose changes.

2. Respect and accessibility

- Have a process in place to truly ensure that all materials used are accessible and in lay-friendly language. Consider the health literacy needs of group members and the format of pre-read materials, for example, written formats versus audio-visual formats.
- Ensure that contracting language is in plain English and that there is enough time during contracting to allow people time to understand, digest and ask questions.

Table 2 Quality assessments across all sample case studies summarised using the seven PFMD PEQG quality criteria

PFMD quality criteria	Summary of quality assessments across all sample case studies	Defined gaps
1. Shared purpose	► This quality standard was considered and discussed for most projects in the context of why people were there, although it was not formalised. ► For some projects, this may not be suitable or required, such as a standalone 1-hour workshop. For others this would be beneficial to prevent confusion, to ensure everybody is clear on the project aim and why they are there, and to ensure everybody feels confident that their views are important and incorporated.	► There was not always a shared purpose written down, accessible for all and frequently revisited.
2. Respect and accessibility	► For all projects, it was important that the timings and set-up of the meetings were planned around people's schedules and family lives. ► It was identified that considering the format of the meetings (face-to-face or virtual) offered wider opportunities, particularly during the COVID-19 pandemic, for improved participation and inclusion of people that may not have been able to get involved previously (ie, owing to reduced time requirements and absence of need for travel). This enables the voices of the less-often heard to be included. This was reflected in the reviewed projects, which were conducted in different ways, virtually and face-to-face, but always in collaboration with an external partner. ► How projects are undertaken, including what type of involvement is needed and whether the group is already formed, or whether individuals were brought together for the remit of the project, needs careful consideration. For example, for already-formed groups with established PPI expertise, codes of conduct may already be in place. However, this may not be the case if the project is undertaken without external partnership, or if it is the first time people have worked with a pharmaceutical company. Consideration of this is important.	► There were no written codes of conduct of what people could expect from Pfizer. ► Language used in contracting and other materials was not always accessible and written in a lay-friendly way. ► Logistics were a challenge for some projects.
3. Representativeness of stakeholders	► Representation and diversity of project groups is a challenge for industry and patient organisations, evidenced in the case studies. ► Although much work was done throughout to ensure that the right people, skills and capabilities for the project were involved, for some of the sample case studies, especially those relating to clinical trials, this was a challenge because of feasibility in practice and the tight timelines leading to a lack of adequate time to do suitable outreach.	► More work is needed to ensure suitable outreach, and robust inclusion and diversity are needed to ensure representativeness.
4. Roles and responsibilities	► In most of the sample case studies reviewed, this was done well, particularly when co-partnering with other PPI organisations. Co-partnering helped patients and carers involved in the projects to have an understanding and familiarity of who they should go to if they had questions. ► For some sample case studies, there was not clear documentation of roles and responsibilities outside of contractual arrangements, which external partners would not be familiar with reviewing. ► For the grant call project, it was deemed important that everyone (patients, clinicians and Pfizer employees) input into all of the stages of the grant call development (ie, research priority setting, request for proposal document, review of applications and decision to provide funding) to ensure alignment and to capture everyone's needs. ► It was considered that including patient co-chairs on research panels should be standard and good practice; this gives the other patients on the panel a feeling of parity of opinion and equity of voice.	► Roles and responsibilities were not always clearly defined and written down for people to refer to.

Continued

Table 2 Continued

PFMD quality criteria	Summary of quality assessments across all sample case studies	Defined gaps
5. Capacity and capabilities	► We saw an improvement over time with this quality criterion. For earlier projects, pre-read materials were not always sent or were not sent in a timely manner. This is now done as standard and was deemed to be very important by the writing group. ► Existing PPI groups were more likely to have had some form of training, whereas newly formed groups will require more assistance in this area. The training could be project specific or general PPI training on what to expect and how to work together.	► Ensuring early on in the project that everybody has the correct skills to enable them to meaningfully contribute is essential, and training should be offered if needed.
6. Transparency in communication and documentation	► This was done well in most projects, with communication plans and documentation storage and accessibility agreed early on at the start of the project so everybody was clear. ► Virtual platforms, when unanimously agreed upon, can allow equitable access to project-related documentation for all. ► Providing feedback in a timely manner is an important consideration and was not always achieved, particularly in projects conducted in earlier years. ► In some instances, more consideration should have been given to the style of communication. For example, the format of materials should be aligned with the group's needs; videos and infographics for the projects including young people were preferred.	► Pre-read materials were not always in an accessible format or sent with enough time to allow information to be digested and questions formulated.
7. Continuity and sustainability	► The projects assessed for this work were mainly short-term projects that were not feasible to sustain and continue. Continuity was achieved by the understanding of how learnings would be implemented. For example, although a specific clinical trial protocol was being reviewed, general learnings were taken back to the development teams for consideration in future clinical research programmes. ► The group agreed that this aspect was of great importance and continued working should be acknowledged and discussed.	► Continuity of work was not always part of the agenda or discussion.

PEQG, Patient Engagement Quality Guidance; PFMD, Patient Focused Medicines Development; PPI, patient and public involvement.

- Develop a code of conduct document. This should be bidirectional and should define what can be expected from all parties. This is especially important for new groups being brought together for a specific project.
- Work as equal partners and be clear about boundaries and roles of stakeholders. Share expertise throughout; external organisations have significant experience that pharmaceutical companies can benefit from.
- Timings and locations of meetings need careful consideration. Think about who is attending, what times would be most suitable and which venues are accessible and comfortable. Online meetings have additional benefits and challenges to consider.

3. Representativeness of stakeholders

- Ensure true representativeness of stakeholders; consider using a sampling framework at the start of each project to determine suitable and appropriate outreach. Sufficient time should be given to do this well.

4. Roles and responsibilities

- At the outset, devise a roles and responsibilities document to use as part of project set-up and conduct. Provide adequate time for everybody involved in the project to share their input and ensure everybody is clear.
- When working with external partners, it is important that all involved provide input into all the stages of development to ensure alignment and agreement of needs. We saw this was particularly important with independent research grants.

5. Capacity and capability for engagement

- Consider who you will be working with and if the group is already formed or is being brought together for the purpose of the project; these will require different approaches.
- Be clear about the type of involvement needed and the skills and capabilities required; develop a template that can be populated for each project.

Table 3 Results and outcomes of the sample case studies in terms of benefits, impacts and challenges to stakeholders

Project title	Benefits and impact to Pfizer	Benefits and impact to patients, carers and other organisations involved	Challenges
Working with patients to review a rheumatology clinical trial protocol	► Understanding patients' perspectives on the delivery of the trial itself; for example, adjusting patient-reported outcome measures, optimising patient symptom diaries or reducing the number of questionnaires to a more practical number for patients. ► Informing the focus of the clinical research plan and providing practical/logistic considerations around trial design for general inflammatory conditions. ► Clarifying the importance of patient insights when developing protocols.	► From the charity's perspective, supporting the voice of people with arthritis in influencing how the study was carried out and how the involvement of patients could be maximised in the study itself. ► For patients, having the opportunity to learn more about a large pharmaceutical company and how feedback can lead to change, ultimately breaking down barriers between pharmaceutical companies and patients.	► Timely project set up. ► Ensuring materials were in truly lay-friendly formats and language and timely communication for feedback. ► Patients felt that insights could have had more impact if involved from the outset, rather than being brought in once it was underway.
Working with young people to review a dermatology clinical trial	► Having the opportunity to understand the perspectives of young people. ► Developing subject assent forms and understanding what young people would like to see included. For example, when shown a cartoon diagrammatic representation proposed for the assent forms, the young people made it clear that they would find it patronising and would prefer to see photographs instead.	► Being able to provide valuable insights that would shape a commercially sponsored protocol to benefit more patients. ► This was the group's first commercially sponsored protocol from a large pharmaceutical company, as opposed to academic protocols historically reviewed by the group. This allowed them to see how different areas of research operate.	► Creating materials and information to describe the study design in plain and clear language, suitable to be understood by a group of young people. ► Confidentiality and role of agreements. ► Time required for PPI managers to gain clarity on what Pfizer wanted and making sessions accessible for young people.
Working with NIHR patient focus group to review two gastroenterology clinical trials	► Gaining a greater understanding of what it is like to live with the condition being studied. ► Receiving thoughts on the study design; feedback from participants was open and insightful and gave greater depth of consideration for obviously invasive and disruptive procedures. ► Clear information on where the patients would look if they were interested in taking part in a clinical trial. ► Insights into the role that treating clinicians play with trial decisions.	► Participating in direct conversation between Pfizer representatives and patient participants. ► Working with an established and trusted organisation (NIHR) gave patients greater peace of mind. ► Allowing patients the opportunity to explain what outcomes they value and would prioritise.	► Logistics, primarily due to weekend meeting requirements. ► Patient information should have been circulated earlier prior to the meeting.
Working with parents and caregivers to review dermatology study documentation	► Understanding how to present the informed consent form and what information should be given, particularly with respect to procedures like blood sampling.	► Feeling their opinion was truly important. ► Understanding that pharmaceutical companies are willing to listen to patients and families. ► Accepting future invitations to support industry-led studies.	► Finding a convenient time for all. ► Ensuring Pfizer materials were in lay-friendly language.

Continued

Table 3 Continued

Project title	Benefits and impact to Pfizer	Benefits and impact to patients, carers and other organisations involved	Challenges
Independent medical grant call: quality improvements in rheumatology practice: delivering change for patients	► Collaborating with patients ensured that there was a patient-prioritised research agenda. ► The research questions and outcomes were relevant to patients and translatable to the NHS. ► Including patient organisation perspectives allowed the research call to be generalisable to the wider community. ► The clinicians involved in the project reported that they found that the process was inclusive, and that the opportunity to listen and learn from the patients and carers would help inform future practice. ► Using learnings gained to optimise ways of working in future projects to enable more patients to be at the centre of decision-making. ► Patient insights were extremely valuable and helped to influence change; eg, the proposal draft received over 50 comments from patients that were incorporated into the final document.	► For the patient organisations, influencing the research call to ensure it aligned with their priorities, which were set in collaboration with external partners and healthcare professionals. ► For patients, feeling involved in the whole process, particularly co-chairing the external review panel, to ensure that the patient voice is heard and considered equally.	► Allowing adequate time for everybody to complete the reviews required. ► Comprehensively incorporating PPI processes within the grant call request for proposals.

NHS, National Health Service; NIHR, National Institute for Health and Care Research; PPI, patient and public involvement.

- Consider any additional training or support that people may require and offer this at the outset.
- Use an established PPI framework or quality guidance and/or a group of experienced PPI representatives to ensure meaningful, high-quality and impactful engagement.
- Do not underestimate the capabilities and value of young people; ensure young people are involved in a meaningful way and not excluded.

6. Transparency in communication and documentation

- Ensure enough information (eg, pre-read materials) is sent in advance of meetings and that this is done in a timely manner in appropriate formats and language.
- Thank people and provide feedback in a timely manner, ensuring that they understand what impact their contributions have had.

7. Continuity and sustainability

- Continually evaluate the meaningfulness, benefits, challenges and impact of PPI in medicines development to enable improvement in practice.

Other general considerations

- There are valuable learnings within pharmaceutical companies, which should be shared openly and in a practical way to improve practice throughout the industry.
- Involve people as early as possible in the process; understand within the organisation where this needs to happen and implement change.
- Patient organisations have significant experience and expertise that pharmaceutical companies can benefit from. They can also gain a better understanding about pharmaceutical companies' approaches to implementing PPI learnings and vice versa. Sharing expertise and evaluating along the way is important.

DISCUSSION

This work was carried out from a multistakeholder perspective, with direct learnings from a pharmaceutical company. Most PPI assessment carried out internally by companies and institutions is rarely shared with the wider community. The initial scoping literature review prior to this work discovered limited published pharmaceutical company experience, with 20.4% of the relevant literature originating from the pharmaceutical industry, demonstrating the need for sharing and reporting of industry findings in the PPI space.

This work therefore recognised from the outset the importance of communicating internal findings and aimed to share learnings from the selected projects, which will provide additional material to the existing literature and improve the PPI knowledge base in a practical way. This review identified some expected challenges,

Table 4 Lessons learnt from the five sample case studies

Corresponding PFMD quality criteria	Lessons learnt
1. Shared purpose	► Time is required at the start of meetings to ensure that a shared purpose is created and consistently reviewed. This is essential for optimal outcomes.
2. Respect and accessibility	► For future projects, a code of conduct—also known as a list of expectations or ways of working documents—should be codeveloped by all involved and implemented. This could be a document or slide outlining what is expected of people and what people can expect from Pfizer, as well as how their feedback will be used. This should be sent to everybody prior to the first meeting or presented at the start of a meeting. This would help the group to understand what mutual respect should look like and to be able to form and respect diverse views. This is especially important for a new group, as existing groups may already have their own codes of conduct in place. ► Language and health literacy should be given thought, time and consideration, and involving patients and carers in drafting of materials is key. Technical research language, when read by a patient, may not only be unclear but actively dispiriting. There is a need to agree on consistent language at the outset. Glossaries of terms can also be very helpful. ► Contracting language should be accessible and explained to patients and other organisations; there should be enough time given for contracting to allow people to understand, digest and ask questions. ► Timings of meetings, the types of meetings and where meetings are held should be given careful consideration, with particular regard to accessibility of amenities.
3. Representativeness of stakeholders	► More planning, time and resources to ensure suitable outreach and representativeness is required. ► The capabilities and value of young people should not be underestimated and should be included in relevant projects. ► This is a call to action for industry, academia and patient organisations to work together.
4. Roles and responsibilities	► At the outset of a project, it is valuable for the project team to review roles and responsibilities and co-create these with patients and carers. ► Having this written down and discussed at project meetings would help to make sure people are clear on what is expected of them.
5. Capacity and capabilities	► Project leads should consider who they will be working with. For example, an already-formed group who are used to working with each other may feel more confident to speak up, compared with a group that has been newly brought together specifically for a project. This will require consideration by the project lead to ensure everybody can contribute equally. ► Using an established PPI framework and/or a group of experienced, trained representatives to ensure meaningful, high-quality and impactful engagement is key.
6. Transparency in communication and documentation	► Ensuring that pre-read materials are sent with plenty of time in advance of meetings. Consideration should also be given to the format of these materials (eg, written vs audio-visual or multimedia materials). ► Consideration should be given to the health literacy needs of the group and the relevance of material types based on the format of the project. ► Feedback should be timely and in a format that is acceptable. It should include enough detail so that stakeholders can understand how their involvement has made a difference.
7. Continuity and sustainability	► Continuity of work should be discussed towards the end of the project and involve listening to ideas, suggestions and views on continued partnership.

PFMD, Patient Focused Medicines Development; PPI, patient and public involvement.

such as the difficulty of addressing and achieving true inclusion and diversity. It also highlighted organisational constraints often associated with the complicated procedures that global pharmaceutical companies have owing to the nature of their activities,[33] noting that not all research timelines are conducive to undertaking suitable outreach activities. This work demonstrated that Pfizer is currently involving patients and carers in many different areas across the medicines development continuum, but there is room for improvement. In the assessed projects, external partners were not involved early on enough in the process to have maximal impact on medicines development, limiting the value they could provide. In the authors' view, these organisational barriers may, in part, be due to delays to starting research when pharmaceutical companies collaborate with external organisations, detracting from the time available.[33] It could also be due to a lack of understanding within pharmaceutical companies of the value of PPI during these early stages and the need to manage shareholder expectations,[34] or it could be due to the global nature of many pharmaceutical companies, meaning that much of the early preclinical and clinical research is conducted outside of the UK.[35 36] For example, regulatory requirements may mean that not all proposed changes are feasible. However, regardless of the stage of PPI, it is the depth and scope of the involvement, as well as honesty and transparency in managing expectations, that will ensure quality and meaningfulness, with meaningful PPI being characterised by providing relevant opportunities to contribute to and have a tangible impact on research.

There are differences in motivations, practices and outcomes of PPI when comparing non-profit and for-profit organisations; these differences can affect how PPI is embedded and developed, and how it is perceived as meaningful. When asked to reflect on and compare experiences of involvement in non-profit versus for-profit environments, our external partners felt that in PPI activities organised by non-profit institutions, people may contribute time and effort for altruistic reasons, and may not always be driven by an offer of financial compensation. These organisations are typically valued and trusted more by the public, whereas for-profit organisations may not be perceived in the same way. PPI activities driven by for-profit organisations may, in some cases, be less impactful, for example, when PPI is not sufficiently considered at all stages of research. Non-profit and for-profit organisations can learn from each other's PPI practices and collaborate on activities, such as through cross-funding on a grassroots level to establish 'profit for purpose' approaches. Cross-industry collaborations can also help to bust myths or assumptions about each other. In terms of defining meaningfulness, our external partners also felt that when PPI is done in a limited or prescribed way, it risks becoming tokenistic, for example, when used solely as a requirement to secure funding or approval. The answer is to strike a balance—involve external partners in all stages of research and in a variety of activities, including contributing to performing research and interpreting results, when possible. PPI is an essential ingredient for furthering science and clinical research and improving health outcomes for communities, and rationale and accountability matter in ensuring quality and meaningfulness. For example, rationales for embedding PPI may come from different places, from wanting to understand impactful best practices through to simply meeting requirements. However, as long as the result is that PPI is fully embedded at an involvement level and not just at an engagement level, its inherent value should become clearly demonstrated over time in terms of outcomes, although the measure of the benefit will vary across organisations, countries and disease areas. Pharmaceutical research has historically been an inaccessible field for external partners, so PPI is an important tool for improving collaboration and understanding between parties and making people aware of how they can positively impact research.

From the perspective of our external partners, there are also considerations to be mindful of in terms of how external partners are given a seat at the PPI table, whether they are explicitly invited or whether they have requested to have their voice heard. Our external partners felt that those who are invited to the table may be afraid of voicing criticism and unpopular opinions for fear of offending the people they have been invited by, and thus not being invited to future consultations. On the other hand, those who apply for a place at the table are likely to be more critical and honest, and thus make more insightful contributions. In addition to how external partners reach the table in general, it also matters which table they are at and under what terms they are at it. If the table is just an echo chamber with no impact on strategy or output, it does not matter how the external partners got there if there is no meaningful effect. This needs to be given thought and consideration and, ultimately, the goal is to inspire and influence a world in which voices are being heard, and collaboration between for-profit and non-profit organisations is a key way that this can be achieved.

This work highlighted that future projects should clarify the shared purpose between stakeholders and have clear roles and responsibilities designated to each from the outset. It is helpful to explain why PPI is being sought and to convey this in an enthusiastic and collaborative way to inspire maximum engagement. Ensuring PPI work is carried out in friendly, approachable and familiar environments allows people to feel empowered and engaged.[37] Familiar environments could be supported by virtual engagements[38] and by working collaboratively with external organisations, such as patient organisations in which people are likely to already feel comfortable.[39 40] The need for trust and rapport is vital, especially when public trust in the pharmaceutical industry may be low.[41] Trustworthiness should be established early on in the PPI process, through collaborative ways of working and mutual respect; contributors need to have the value of their input recognised by being thanked and given the opportunity to provide feedback in a timely manner. This was evidenced in this work, in which external partners commented on the positive benefits of working with a pharmaceutical company and felt their opinion was truly important and that pharmaceutical companies were listening to patients and families. Through PPI activities and continuous sharing of learnings, patients, carers and patient organisations are able to gain a general understanding into pharmaceutical companies' approaches and vice versa. Such dialogues and interactions may even help to dispel preconceived notions each party may have about the other.[42] Accessible language and formats of materials are vital when establishing rapport and engagement. It is important to be mindful of being accessible without being patronising. Language is an important enabler of meaningful involvement, but can also create barriers.[43] In recognition of this, a glossary of terms was developed to supplement this paper (online supplemental appendix 9). Health literacy principles should be embedded into materials development; Pfizer is implementing robust staff training for health literacy and expects its principles to be applied throughout the conception, development and approval of health information materials. Furthermore, relevant UK contracts are being rewritten to be more easily understood and aligned with the health literacy and readability needs of the public; other documentation is also being reviewed to improve the understandability and accessibility of information. Accordingly, informative pre-read materials that are provided to people must be carefully considered in terms of format and content to ensure information is conveyed in a way that is accessible to the

target audience. Useful formats can include PowerPoint slides and PDFs, but there is scope to use more imaginative and novel formats when suitable, particularly when engaging with young people.[44–46]

Based, in part, on the authors' interpretations of these learnings, Pfizer has recently undertaken several actions to overcome some organisational challenges that may limit the capacity for and effectiveness of PPI identified in this quality assessment. These include incorporating new roles within the UK medical and policy teams specific to partnering with patient organisations, patients and carers. Pfizer has also produced internal company training on meaningful PPI as part of an initiative to raise awareness of the importance of patient involvement and to align with Pfizer's overall aim of 'being known as the most patient-centric organisation'. Further to this, Pfizer is devising templates for systematic, efficient and meaningful engagement with people to gain maximum feedback, while being respectful of the value of each person's time. Ultimately, PPI is not a quick fix but an initiative that needs long-term investment of time and resources.[47 48] Considering all of the above will allow inclusion of a more diverse and enduring patient voice across medicines development.

Limitations of this study

Limitations of this study included the selection process of a relatively small manuscript writing group. Because Pfizer has conducted many PPI projects across medicines development and across therapy areas, not all voices could be included in this assessment, potentially leading to a lack of representation. Opinions of the group may also not be representative of the wider public and particularly of demographics that are typically under-represented in research, such as healthy young people or migrant populations. However, it should be noted that, although PPI and representation cannot provide the definitive voice, for example, of the public or of a patient group, it still provides an important voice. The external validation step of the case studies was employed to help counter this limitation. This work was also UK-specific and the findings need to be viewed in this light. As many pharmaceutical companies have global headquarters and operations, the distribution of projects across the medicines development continuum may differ, particularly in the earlier phases.[35 36] Further research is required to draw conclusions about PPI in medicines development in a global context. In the time since starting this work, PPI across medicines development in Pfizer has expanded and additional case studies have been assessed; these may add value as part of a subsequent review to look at a greater breadth of projects for improved representation. Furthermore, this manuscript represents the work and views from a single pharmaceutical company. Future work should expand what has been learnt here as a cross-industry collaboration. Lastly, retrospective analysis is challenging and subject to recall bias.[49] This was evidenced in the external validation feedback, in which one patient reviewer noted the age of the projects and the difficulty in remembering details. Involving several individuals in writing and reviewing the case studies may have helped close any recall gaps.

Strengths of this study

The manuscript writing group was heterogeneous and represented different stakeholders groups including industry representatives, patient organisations, NIHR representatives, carers, young people and adult patients. The diverse range of voices and perspectives enabled a greater ability to draw meaningful conclusions from this research; future groups may consider learning from these experiences. This work was systematically carried out against an established framework, which is considered a valid and robust tool.[29] External validity assessments were also employed to incorporate as many voices and views as possible. The results of this work will be used by Pfizer to refine a PPI improvement and implementation action plan that is currently in development. This work provides value by contributing to the limited literature and raising awareness of the importance of meaningful PPI in the pharmaceutical industry and may be particularly informative for organisations and individuals wishing to partner with pharmaceutical companies. It also has translational benefits for PPI in future medicines development activities across the Pfizer global organisation and for other industry professionals.

CONCLUSIONS

There is wide acceptance that PPI in clinical research and medicines development is impactful and meaningful for all parties involved, but it is still developing and, while there has been good progress within pharmaceutical industry research, further improvement is needed.[12–14] This includes involvement early on in medicines development so that maximum input can be achieved at all stages. There is already established PPI guidance available,[6–11] but, to overcome organisational challenges and to embed PPI consistently and comprehensively throughout all stages of medicines development, it is the authors' views that pharmaceutical companies should have a dedicated team or role whose focus is PPI, with resources and capacity appropriately allocated. PPI must be genuine and empowering for people and not tokenistic or a 'tick-box' exercise; trust and rapport from the outset is vital. External partners need to feel that their contributions are being genuinely valued and used. It is also important to respectfully give thanks for their time and to ask for feedback of their experience of involvement so that lessons can be learnt. Here, the PFMD PEQG tool enabled useful reflection to define gaps, establish learnings and devise recommendations for future improvement. The recommendations presented in this work represent Pfizer's efforts to share learnings with the wider PPI community and industry, and are already a starting point for continuous improvement of future practice within Pfizer. Ultimately, these recommendations should be acted upon to further embed PPI as an integral part of

medicines development and health research within the pharmaceutical industry.

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Funding This work was funded by Pfizer, UK. Medical writing support was provided by Adeline Rosenberg of Oxford PharmaGenesis, UK, also funded by Pfizer, UK.

Competing interests S-AD, SB, LC, SE, SH, BP and NB are employees of Pfizer and hold Pfizer stock. AB, RD, AD, EK, GP, JP and KS have no competing interests to report.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Additional data beyond what are provided in the supplement may be made available upon reasonable request to the authors.

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