Medical writers moving the needle on patient-centred communication and engagement

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Abstract

Patient and public involvement and engagement (PPIE) in clinical trial design, conduct, and reporting provides an opportunity for patients and members of the public to provide input on what is important to them. This supports patient-centric trial design, more efficient trial conduct, and more transparent trial reporting. Patient input can enhance the trial's purpose by ensuring the trial's goals are meaningful and relevant, can allow exploration of the barriers and facilitators of compliance and adherence, improving recruitment and retention, and can ensure that studies address real-world issues. Medical writers can support the communication of PPIE activities across the clinical trial lifecycle through clear and effective writing.

Good clinical practice and ethics guidelines have always emphasised the rights of clinical trial participants.[1,2] This focus has sharpened over time, shifting the role of patients from passive participants to active partners in the research process and giving rise to Patient and Public Involvement and Engagement (PPIE) initiatives. PPIE promotes the "Nothing About Us Without Us" statement, where patients and the public regularly contribute their insights throughout the clinical research process.[3]

Public contributors include not only trial participants but also individuals with a disease or condition, members of patient advocacy groups, caregivers or family members, and providers of social services.[4] By providing real-life lived experiences, they can provide meaningful insight into the disease or condition being investigated (Figure 1). Adopting a more patient-centric approach can ensure that the design and conduct of clinical trials are tailored to the needs of the participants and limit the increasing complexity and cost of clinical research.[5]

PPIE is not one-size-fits-all. Country-specific regulatory frameworks provide a variety of ways through which public involvement can improve the relevance and quality of research. These frameworks provide a mutually beneficial environment in which all trial stakeholders can work together.[6-15] To understand the full impact of PPIE, let us examine how patients can influence clinical research throughout its lifecycle.

From design to dissemination: how patients can influence clinical research

Patients' unmet needs are the main driver in the development of medicines. Researchers now recognise that PPIE can improve the quality of clinical trials (Figure 2). Patients, caregivers, and the public can be involved at all stages of a clinical research project.[16] They can set and refine research questions based on their perspectives and lived experiences, for example, by providing input on endpoints that are meaningful to them. They can also participate in key decisions relating to the design and conduct of trials, such as identifying appropriate eligibility criteria and selecting benefit and risk assessments. Patients and the public can explain how they engage with instruments and activities, helping researchers determine the most effective way of assessing patient-reported adverse events, outcomes, and quality of life. Additionally, patients and the public can support the dissemination of research findings by participating in patient reviews and contributing to lay summaries. Patients can also act as reviewers and co-authors of peer-reviewed journal publications resulting from clinical research.[17]

The TransCelerate P-PET User Guide[18] is a practical resource that helps clinical research teams systematically incorporate patient and public input early in the clinical trial protocol development. It recommends that research teams responsible for the design, planning, and conduct of a clinical programme or clinical trial should consider implementing PPIE as early as possible in the clinical trial protocol development lifecycle. Doing this can boost the success of a clinical trial in several ways, such as:

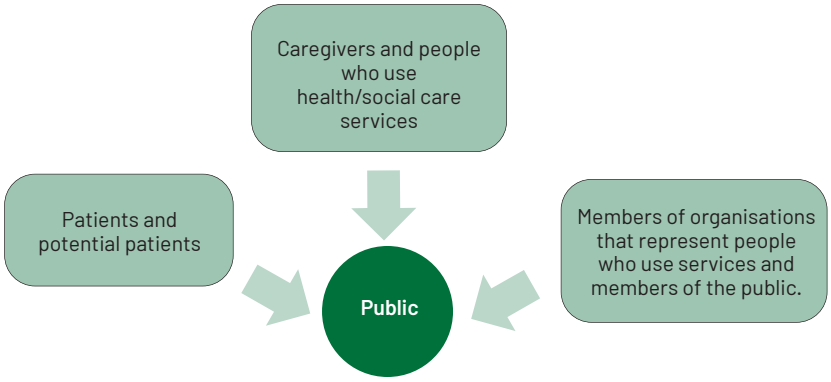


Figure 1. Who represents the public when designing clinical research?

- **Aligning a clinical trial with the experiences, preferences, needs, and concerns of people with lived experience which is crucial for developing effective therapies.** Scientists and those living with a disease or medical condition may interpret "unmet needs" differently, leading to potential oversights in important outcomes, such as symptom scores or quality of life measures that affect an individual's ability to live a full life.[19] To address this and incorporate patient perspectives effectively, several strategies can be implemented:
  - Early engagement: Involve patients in trial design through focus groups or advisory boards.
  - Protocol development: Include patient representatives on review committees.
  - Endpoint selection: Incorporate patient-reported outcomes alongside traditional clinical measures.
  - Informed consent: Collaborate with patients to create clear, understandable documents.
  - Trial implementation: Consult patients on schedules and procedures to minimise the burden.[19-21]
- **Increasing participant enrolment and retention in research.** Patients may feel more inclined to participate in trials that are inclusive and transparent, represent their needs and interests, interfere little with their daily lives, and avoid unnecessary discomfort.[22] Patient insights can also support clinical trial protocol design. For example, clinical trials with lengthy and complex clinical procedures and unnecessarily invasive diagnostic procedures are likely to be unattractive to patients and to have poor recruitment and retention.[21,23] Pharmaceutical companies that decide not to implement patient input into the protocol or do it too late may face enrolment and retention challenges, as well as increased costs and time needed to complete their trials (Figure 3).[21]
- **Building trust.** Including patients in decisions about trial design and dissemination may help trial participants feel more in control of the process and outcome, foster trust and collaboration, and broaden the impact and application of the findings.[24]
- **Improving relevance, quality, and outcomes of drug development.** Soliciting patient input early in the drug development process can identify endpoints that address unmet needs that are important to them.[25] Clinicals using trial endpoints based solely on pathophysiology may miss aspects of the disease that affect quality of life or increase burden on patients.[26,27]

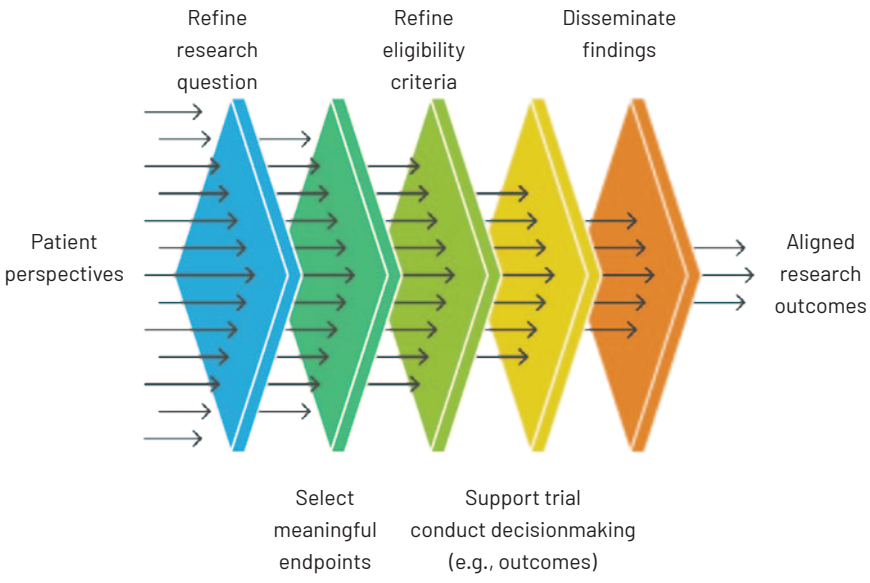


Figure 2. Patient and public involvement in research stages

Guidelines and standards for effective PPIE in research

Many global initiatives have developed frameworks, training, and tools to enhance PPIE in clinical trials (Table 1). The National Institute for Health Research in the UK provides comprehensive guidelines for incorporating patient perspectives in all stages of research to ensure inclusivity and diversity in clinical trial design

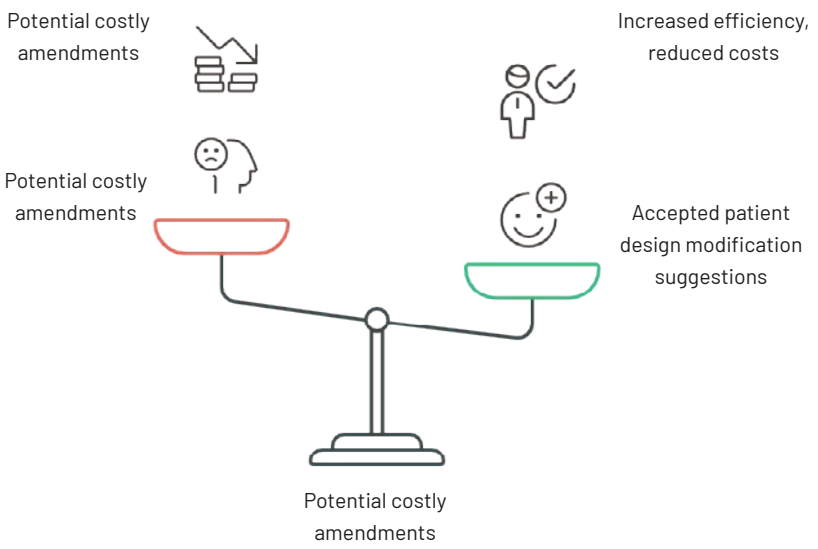


Figure 3. Timely patient feedback enhances protocol efficiency

and implementation.[2,8] The Patient-Focused Drug Development and the Patient-Centred Outcomes Research Institute in the US provide guidelines to design research around patient's concerns and priorities.[6,7] The European Patients' Academy on Therapeutic Innovation provides education and training initiatives for patients, as well as guidance for including PPIE in ethics committees, regulatory authorities, and health technology assessments, further embedding the patient's voice in the drug development process.[8–11] Additionally, initiatives like TransCelerate's Patient Experience[12] and Clinical Trials Transformation Initiative[13] emphasise involving patients and caregivers early in trial design and execution, with the aim of improving feasibility, recruitment, and retention, and ensuring trial outcomes reflect real-world patient experiences. Also, the Public Involvement Impact Assessment Framework[14] and Guidance for Reporting the Involvement of Patients and the Public[15] chart and assess the impact of PPIE in research, ensuring that clinical trials continually improve based on patient feedback.

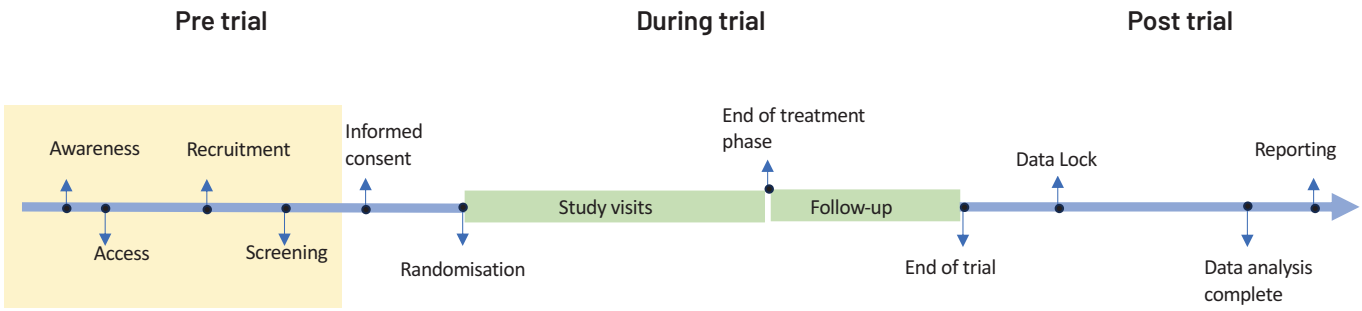
While these guidelines provide a framework for PPIE, implementing effective patient engagement strategies is crucial for their success.

Patient engagement strategies

Clinical trial researchers must balance patient input with scientific understanding and business, legal, and regulatory requirements. Researchers have traditionally used unidirectional approaches, like surveys or questionnaires, to gather feedback on trial participants' experiences, but they have been shifting towards strategies that

Table 1. Global frameworks and initiatives for patient engagement in clinical research

Organisation/Initiative	Description	Link
Clinical Trials Transformation Initiative (CTTI)	Recommendations for patient group engagement in clinical trials	CTTI Recommendations
European Patient Academy (EUPATI)	Network supporting patient involvement in medicines research and providing training across Europe	EUPATI
Guidance for Reporting Involvement of Patients and the Public (GRIPP2)	Reporting checklists for improving documentation of patient and public involvement in research	GRIPP2 Checklist
National Institute for Health and Care Research (NIHR)	UK standards for public involvement in research	NIHR Standards
Patient Centred Outcomes Research Institute (PCORI)	US standards and engagement rubric for patient centred research	PCORI Standards
Patient-Focused Drug Development (PFDD)	FDA guidance on collecting and submitting patient experience data for medical product development	PFDD Guidance
Public Involvement Impact Assessment Framework (PiiAF)	Framework for assessing the impact of public involvement in research	PiiAF
TransCelerate Patient Experience (PE) Initiative	Initiative to improve patient experience in clinical trials	TransCelerate PE



- Aim for demographic diversity in regional and site selection
- Engage communities
- Provide education to improve population research readiness
- Develop action plans and targets for representativeness, aiming for a participant-to-prevalence ratio of 0.8-1.2
- Use broad inclusion criteria

- Simplify and customise the informed consent process
- Apply strategies to make trial participation less burdensome
- Provide cultural competency training
- Ensure representation among investigators and trial committees
- Ensure that sociodemographic information is collected and reported
- Consider novel trial designs
  - Embedded
  - Registry-based RCTs
  - Decentralised
  - Adaptive
- Monitor the representativeness of participants through interim analyses

- Ensure data protection
- Provide plain language summaries including culturally competent, accessible information
- Involve participants indissemination
- Engage diverse investigators in the authorship of primary and secondary anaysis

Abbreviations: RCT: randomised controlled trials.

Figure 4. Strategies to increase representativeness in clinical trials

increase involvement, collaboration, and engagement with patients and caregivers (Figure 4).[21]

These strategies include conducting periodic surveys to gather input on clinical trials, partnering with patient advocacy groups and caregivers to keep abreast of patients' unmet needs, and maintaining a bank of patient insights for key opinion leaders and scientific staff to consider when designing clinical trials.[29] Following are additional suggestions for strategies to improve patient engagement:

- **Create organisational standard operating procedures (SOPs) for patient engagement.** SOPs that consider local regulations can be used to define roles and responsibilities for patient partners, patient advocates, and pharmaceutical industry stakeholders.[30] When used as a standardised framework, these SOPs ensure quality, consistency, and relevance in patient engagement strategies, while allowing room for adaptation and accommodation of different therapeutic areas. A standardised internal process can help maintain ongoing, mutually beneficial partnerships between researchers and patient partners; establish knowledge banks of patient insights, develop contextual online surveys, or organise virtual meetings with patient partners to help prepare for clinical trials; and ensure timely stakeholder feedback before initiating or modifying clinical trial protocols.
- **Allocate budget, timelines, and resources to support patient engagement.** Dedicated budgets may be needed for infrastructural costs, preparation and delivery of training and educational materials, compensation (financial or non-financial) of patient partners, and translation of patient input into actionable research strategies by key opinion leaders. Putting these patient engagement strategies into action and managing timelines for them will also require adequately trained resources and their management by strategic leads.[21]
- **Specify goals for patient engagement initiatives.** The backgrounds, perceptions, and interests of researchers and their patient collaborators may not always be aligned.[5] To avoid potentially costly conflicts and delays, expectations and rules of engagement must be clarified from the outset.[31] Key aspects include: having a simple contract of understanding and confidentiality or non-disclosure agreements to protect the researcher's interests; compensating participants; having a regular touchpoint with participants; developing a plan for how the data resulting from patient engagement activities will be collected, shared, stored, assessed, and utilised in designing the trial; and establishing the role of an institutional review board.

With the increasing emphasis on PPIE, medical writers play a crucial role in ensuring that patient perspectives are effectively integrated into all aspects of clinical trial documentation and communication.

The role of medical writers in integrating patient perspectives

Medical writers play a crucial role in ensuring that patient experiences and insights are included in research materials, such as clinical trial protocols, lay language summaries, thank-you communications, and educational materials. Also, according to regulatory requirements, clinical trial results must now be shared with study participants.[32] This implies translation of complex medical concepts into plain language for a range of non-specialist audiences. Medical writers can help bridge the gap between researchers' intentions and patients' needs by creating well-crafted, patient-facing materials that are not just scientifically accurate but also inclusive and accessible to patients.

Table 2. Medical writer considerations for incorporating patient input into clinical trial protocols

Protocol element	Patient input	Medical writer considerations
Trial objectives and endpoints	Unmet needs, disease burden, important endpoints	Clearly articulate patient-identified unmet needs and how trial objectives address them. Explain how objectives or endpoints that are important to patients have been incorporated.
Trial design	Concerns about travel, invasive procedures, technical support needs	Describe what patient input has been achieved and how the trial design accommodates patient preferences (e.g., decentralised visits, minimised invasive procedures). Explain any patient support systems in place.
Eligibility and participation	Representation, support during screening, withdrawal process	Highlight how eligibility criteria have been modified to encourage diverse representation. Clearly describe the informed consent process, including withdrawal procedures.
Trial drug	Administration concerns, expectations about side effects	Explain how patient concerns about drug administration are addressed. Clearly communicate expected side effects and their management.
Patient-reported outcomes (PROs)	Relevance, complexity, administration of PROs	Describe how PROs were selected or modified based on patient input. Explain measures taken to ensure PRO accessibility and ease of completion.
Trial results	How and when patients will receive results	Clearly state in the protocol how and when trial results will be communicated to participants.

Incorporating patient input into clinical trial protocols

Medical writers can weave patient experiences and insights into clinical trial documents. Starting with the clinical trial protocol, the writer can make it clear that patient input into the document is an expected part of the clinical trial design. This should be expected by the trial team because most clinical trial protocol templates (based on the Common Protocol Template by TransCelerate) include a subsection on patient input into the trial design.[33] Also, recent ICH E8(R1) and ICH E6(R3) guidance highlights the need for a "Quality by Design" approach, where quality factors are built into the scientific and operational design of the trial, ensuring that the trial meets its objectives.[1,34] Patient input into the trial design is a fundamental part of this approach. In alignment with this, the medical writer can ensure that patient input is transparently included in the clinical trial protocol (Table 2). This information can be reused or repurposed at later stages in the clinical trial.

Adapting language for diverse audiences

Medical writers optimise accessibility and understanding of communications by tailoring them to the targeted cultural backgrounds and literacy levels. Although approximately three-quarters of clinical trial participants value receiving lay language summaries, including the trial results, only approximately one-third actually receive them.[35] About 90% of clinical trial participants are likely to enrol if they know that a study summary will be provided after the trial.[35] Medical writers can help by creating clear, concise, and accessible summaries that translate complex scientific terms into understandable language.

Improving recruitment and retention materials

Over 20% of patients either trust the medical decision of the investigator for their enrolment or are unaware that clinical trials involve more clinical visits and tests than standard care.[36] Medical writers can help by producing informed consent forms that include plain language descriptions of the clinical trial and incorporate patient feedback to better reflect patient priorities. Medical writers can collaborate with patients and the public to develop relatable messaging that addresses their concerns and explains how the clinical trial has been adapted to suit their needs. Retention can also be improved by connecting with trial participants and supporting them with follow-up communications.[37] Medical writers may also collaborate with patients to create recruitment materials that address common concerns and emphasise the benefits of participating in clinical trials and to produce follow-up communications that can enhance retention.[38,39]

Concluding remarks

PPIE has become an essential part of clinical trial development. Medical writers are well-positioned to support it by asking targeted questions when developing clinical trial documentation and ensuring that these insights are communicated throughout the trial lifecycle and the documents. Detailed and accurate reporting of PPIE helps increase its visibility and promote its adoption by the clinical research community.

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The opinions expressed in this article are the authors' own and not necessarily shared by their employer or EMWA.

Disclosures and conflicts of interest

The authors are employed by Parexel International Ltd.

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