Guidelines for a patient-centred application

The FORCE consortium stimulates researchers to conduct patient-centred research. In this document, we provide you with some explanations about patient involvement in research, how to conduct meaningful patient involvement, and some tips and tricks for patient-centred research and good patient involvement.

General tips

These guidelines form instructions on how to write a clear project proposal for the patient advisory committee (PAC).

- Be objective and honest in your application. Ensure that the application submitted to the Scientific Expert Committee (SEC) and the Patient Advisory Committee (PAC) are fully consistent with each other.
- In addition to providing a clear and concrete rationale in the project application, ensure that your arguments are structured logically.
- Use clear figures and diagrams to support and illustrate your rationale.
- The application should be written in a way that is clear, accessible, and relevant to patients. Have the content and language reviewed by one or more patients from the target group and actively seek their feedback on both the content and the design of the project proposal.
- Check the final document for typographical or visual errors before submitting the project application.

Patient-centred research

Patient centricity means the focus of the project should be on the needs and wishes of patients. People affected by cancer should be directly involved in the research development process.

The **patient perspective** encompasses the lived experiences of patients regarding illness, healthcare, and the impact on their lives. The aim of capturing this perspective is to translate it into actionable input for research and strategic decision-making. This perspective is not automatically available and must be actively gathered. Researchers therefore have the responsibility to apply a clear methodology to translate the patient perspective into concrete recommendations, research choices, and strategic decisions.

TIPS

- Ensure sufficient attention is given to clearly defining and substantiating the **concrete need and added value** of the research. Did the research question originate directly from patients within the target group? If so, clearly describe the research question and the collaboration with these patients in the application.
- If the study builds on results from previous studies, clearly **describe the status and outcomes of these studies**. Explain how these results will contribute to the proposed research project.

- Clearly define the **inclusion criteria** for the clinical study. Why were these criteria chosen? Do they exclude certain patient groups, and if so, what alternatives are available for patients who cannot participate?
- Consider the **accessibility of the treatment** after the project has ended. Is there already a plan for collaboration with other international centres?
- In addition to improving life expectancy, **improving the quality of life** is of great importance. Ensure sufficient attention is given to the quality of life of participating patients, as well as the potential disadvantages of participation. Include appropriate monitoring of patient burden (physical, mental, financial, practical, etc.) throughout the study.
- Participation in a study may involve risks. Has a **cost–benefit analysis** been conducted, and has this been adequately discussed with patients? What potential risks or impacts might participating patients experience?
- Pay sufficient attention to how study participation is discussed with patients. How will the expectations of participating patients be managed? Also consider how potentially disappointing or negative study results will be communicated to participants and how their expectations will be addressed throughout the study.
- Depending on the context of the study, **interim analyses** may facilitate the earlier communication of results to (participating) patients.
- Consider the continuation of your research and the **implementation** of results after the project ends and ensure the patient perspective remains central in this process.

Meaningful Patient Involvement: what, why, who, when and how?

WHAT?

Patient involvement means that patients are actively involved in, and have influence on, decision-making processes, including in research. It is not a goal, but a means to incorporate the patient perspective and ensure that the patient voice is embedded.
The term itself does not define the values associated with it. It is therefore important to explicitly address the following questions:

- How is involvement structured?
- To what extent is patient involvement taken seriously?
- How much influence do patients actually have?
- What is the purpose of the involvement?

A common pitfall is **tokenism**, which occurs when patients or public members are included in research processes merely to fulfil a requirement or to give the appearance of inclusivity. Their input is often not genuinely valued, and their participation does not influence decisions meaningfully. Patient involvement therefore means more than simply ‘taking part’, ‘being present’, or ‘attending’. When involvement is limited to this, it cannot be considered true patient involvement.

WHY?

Involving patients is a prerequisite for making well-informed decisions in healthcare, policy, and research[1]. It ensures that decisions are based not only on scientific and clinical knowledge, but

also on the experiences and needs of patients themselves. Patient involvement has become a standard practice worldwide and is also indispensable for FORCE.

Experiential knowledge provides valuable content: patients have a unique perspective on their disease and everything surrounding it, such as living with the condition, the care pathway, recovery, and sometimes facing incurable illness. The patient perspective complements the knowledge and expertise of researchers. This can lead to more relevant research questions or themes, research outcomes that better align with patient needs, more successful inclusion, lower dropout rates during follow-up, improved interpretation of data, and more effective dissemination and implementation of research results in practice.

Patient involvement is therefore a means to **improve**, for example, the **quality of care** and the **relevance of research**. The likelihood of successful implementation of results (e.g. in healthcare decisions, guidelines, research, or policy) increases when all stakeholders - including patients - are involved early in the research process.

WHO?

Different roles can be distinguished within patient involvement. Each role brings its own perspectives, strengths, and limitations.

- **Patient**: A cancer patient is someone receiving medical or nursing oncological care. The patient requires care and is under the supervision of an oncology healthcare professional.
- **Expert by experience**: An expert by experience has processed their own experiences sufficiently to reflect on them with some distance. They are able to go beyond their individual experience (i.e. bring together collective experiences), articulate these clearly, and ensure they are relevant and up to date. Optionally, these experts by experience have completed formal training and obtained a diploma or certificate demonstrating competencies as an expert by experience.
- **Patient representative**: This is someone who represents a group of patients and is able to incorporate the (current) experiences, concerns, and needs of that group into their contributions. A patient representative is often a patient or a relative, but this is not always the case; in some patient organisations, a policy officer without lived experience may take on this role.

For the sake of consistency and readability of the application form, the term ‘patients’ is used throughout.

WHEN?

Patient involvement can add value at different stages. Ideally, patients are involved as **equal partners from the very beginning of a research project**. This helps prevent a mismatch between researchers’ priorities and patients’ needs. However, even if your research has already started, it is **never too late to involve patients**. Below are the key situations in which it is valuable to actively engage patients.

Patient involvement can be applied in:

1. **Specifying research questions**: Involving patients in a research agenda. Involving patients in specifying research questions increases the social and societal relevance of health research.
2. **Writing a research proposal**: Involving patients for relevant and feasible research. Nowadays, many funding bodies require more than just a letter of support from a patient organisation.
3. **Data collection**: The input of patients can also be important during the implementation of your project.
4. **Analysis and dissemination**: For new findings and more useful outcomes. The patient perspective can provide an important lens through which research findings are interpreted, helping to ensure that analyses and the dissemination of results reflect outcomes that are relevant and meaningful to patients.

HOW?

How can patients (and patient organisations) support your research? Examples are:

- Take a **proactive** approach and initiate collaboration with patients from the start of your research. For example, contact a patient organisation and present your research plan during one of their meetings.
- If your research focuses on a very **small or vulnerable patient group** for which no patient organisation (yet) exists, there are still some ways to incorporate the perspectives of these patients into your research.
    - Seek feedback or collaboration directly from your own patients.
    - Seek feedback or collaboration from relatives of current or former patients.
- Include patients in your **steering committee** and involve them actively in regular (e.g. weekly or monthly) meetings.
- Do you already have a developed idea or concept? Ask a patient organisation whether they foresee any **barriers** to data collection or patient inclusion - for example, whether the burden on participants is acceptable or whether the inclusion criteria are feasible. Patient-centred research reduces dropout rates[2].
- Do you have an **informed consent form**? Have it co-written by a patient or patient organisation.
- Establish **patient support groups** when conducting a clinical study or research project. This allows participating patients to share experiences, which can increase involvement and reduce dropouts.
- To ensure effective collaboration between patients and researchers, it is important to openly discuss **roles, expectations,** and **preferences**, and to adapt your way of working accordingly.
    - Is it clear to all parties what the purpose of patient involvement is? For example, to bring in the patient perspective, test assumptions, or support decision-making.
    - Has it been considered and agreed on how patient involvement will take place? For example, through a formal or informal role, advisory group, individual consultations, or group discussions.
    - Is it true involvement (i.e. involvement with influence), rather than merely consultation, questioning, informing, or dialogue?
    - What level of influence do patients have: decisive, advisory, or complementary to other perspectives?

- How much freedom do patients have to introduce topics, including those beyond predefined themes?
- How diverse is the group of patients involved, for example, in terms of tumor type, age, gender, cultural background, or socioeconomic status?

How to keep patients informed about your research

- **Inform** patients and the general public about the impact of your results. Communicate your findings, even if the outcomes are not as expected.
- Patients and patient organisations can **help disseminate information** about ongoing clinical studies or projects in which patients can still participate.
- Patients can also act as **ambassadors** for the project and help communicate results, provided they have been involved throughout the entire project.
- Choose **appropriate communication** channels to reach patients, such as articles, information sessions, leaflets, or social media. Researchers are encouraged to co-write articles with PPI-contributors.
- Organise an **information session** to present (interim) results to participating patients and consider inviting patient organisations. This also allows patients to ask questions about the research.
- Write an article presenting the results in an **objective and accessible (lay) language**. Publish findings not only in scientific journals but also in outlets accessible to patients and the general public.
- Organise an **information day** within your department where ongoing research is presented to patients and the public. Researchers can present their work (e.g. via posters) and patients can ask questions. Promoting regular interaction between researchers and patients contributes to more patient-centred research.
- Do you have an article or poster intended for a patient audience? Have it co-written by a patient organisation before publication.

TIPS FOR THE APPLICATION

In general, it is very important that all completed and planned activities related to patient involvement are described as **concretely** as possible in the application for the Patient Advisory Committee (PAC), for example:

- How will collaboration with patients (and/or patient organisations) be established?
- Why are you involving patients (and/or patient organisations) in your research?
- Who will these patients (and/or patient organisations) be?
- What does the step-by-step plan look like, and at which stages of the research will patients (and/or patient organisations) be involved?
- What questions have been or will be asked to patients (and/or patient organisations)?
- What feedback has been received?
- How has or will this feedback be implemented in the research?
- How will results be communicated back to participating patients and the broader target patient group?

Relevant websites

- **Definitions patient involvement:** https://www.involv.nl/kickstarter-definitions
- **Participation matrix (role of patients in research):** www.participatiematrix.nl

- **Cancer Patients Europe:** https://cancerpatientseurope.org/
- **EUPATI:** https://eupati.eu/
- **EURORDIS European Reference Networks:** https://www.eurordis.org/our-priorities/european-reference-networks/
- **Nederlandse Federatie van Kankerpatiëntenorganisaties:** https://nfk.nl/
- **Guiding researchers and advocates to scientific partnerships:** https://graspcancer.org/join-us/

References

[1] Gobat, Nina, Slack C, Hannah S, Salzwedel J, Bladon G, Garcia Burgos J et al. Better engagement, better evidence: working in partnership with patients, the public, and communities in clinical trials with involvement and good participatory practice. The Lancet Global Health. April 2025.

[2] Fischer SK, Patient-centric clinical trials: collaboration and innovation in bioanalytical and clinical operations. Bioanalysis. January 2025.