FACT SHEET

Patient and public involvement (PPI)

Patient and public involvement (PPI) in clinical research can be defined as research carried out *with* or *by* patients and members of the public rather than *to*, *about*, or *for* them.[1] This means that patients and members of the public become actively involved in shaping the goals, design, and evaluation of research projects by sharing their specific experience with a disease.

What is considered patient and public involvement (PPI) in clinical research

Examples of PPI include (but are not limited to):

- using patient input to identify research priorities
- determining patient-relevant clinical endpoints
- including patients/members of the public in a research project's advisory or steering group
- asking patients/members of the public to comment on and develop patient information leaflets or other research material
- having patients/members of the public support the dissemination and publication of study results.

This is the SCTO's understanding of PPI. There is no harmonised terminology for the concept yet, so different terms can be found. While the term *patient and public involvement* is consistently used in the UK, the terms *patient-focused drug development* and *patient engagement* are more commonly used in the US and Canada.

What is *not* considered patient and public involvement (PPI) in clinical research

Taking part in a clinical study as a study participant is **not** considered PPI. In this role, the patient participates in research but does not actively shape it.

Definition of terms

Involvement: patients and members of the public are **actively involved/engaged** in clinical research projects as full partners

Participation: patients and members of the public **take part** in a clinical trial, usually by providing health data

Why PPI should be integrated into clinical research

Patients can offer a unique perspective on research. Through their experience with a disease or condition, patients know best what matters most to them. By sharing this specific knowledge, they can contribute to the quality, appropriateness, relevance, and credibility of clinical research.[2] From an ethical point of view, one can argue that patients should have an influence on research that affects them, along the lines of the motto **"nothing about us without us"**.[3] There is evidence that PPI leads to more realistic estimates of actually needed recruitment rates and can improve the enrolment rates in clinical trials.[4] Researchers who receive public funding for their projects are accountable to the public.

For in the end, **today's clinical research is tomorrow's medicine**.

As part of its **investigator-initiated clinical trials (IICT) programme**, the **Swiss National Science Foundation (SNSF)** is requesting applicants to document their efforts and plans to actively involve patients, patient organisations, members of their family, caregivers, and the public in the design and delivery of their research projects. PPI representatives are members of the programme's international

[1] INVOLVE (2012). Briefing notes for researchers: Involving the public in NHS, public health and social care research. https://www.invo.org.uk/about-involve/, accessed 3 Oct. 2020.

[2] Gradinger, F. et al. (2015). Values associated with public involvement in health and social care research: A narrative review. *Health Expectations* 18(5): pp. 661–675.

[3] Charlton, J. (1998). *Nothing About Us Without Us: Disability Oppression and Empowerment*. Oakland: University of California Press.

[4] Crocker, J. C. (2018). Impact of patient and public involvement on enrolment and retention in clinical trials: Systematic review and meta-analysis. *BMJ* 363:k4738.

evaluation panel and evaluate the PPI aspects of the planned clinical trials.[5]

How to involve patients and the public in clinical research

There are different methods for actively involving patients and the public in the research process. The choice of methods depends on the target group, objective, timing, and context of involvement. An essential aspect in the selection of methods is the level of intensity of patient involvement. In principle, the following levels of PPI can be identified:[6]

- Patients and the public provide information, e.g. propose outcome measures/study endpoints that matter most to them (see Figure 1, appendix).
- Patients and the public are consulted on specific questions and provide advice.
- Patients and the public are involved at a decision-making level.
- Patients and the public take over/lead specific parts of an initiative, project, or clinical trial.

Which phases of clinical research can include PPI

PPI can occur during individual phases or during the entire research process. PPI representatives can be involved in planning as well as implementation, evaluation, and the dissemination of clinical research results.[7] Ideally, patient involvement should occur before the start of a study so that patients' perspectives have already been taken into consideration when research priorities are identified.

Following a typical research process, Figure 1 (appendix: Possibilities for PPI[8]) shows where patient and public involvement can occur and provides a few examples (not comprehensive).

Who should be involved in clinical research

This question should always be considered in the context of a specific study and while taking into account the key objective of patient involvement. Broadly defined, the term *patient* can refer to any member of society. Depending on the research project, it may be useful to include patient representatives from patient organisations, relatives, or caregivers with a **diverse background** of experiences.[9]

Before involving patients, researchers should define inclusion and exclusion criteria for their target group, such as age, gender, demographic characteristics, and type of disease. The criteria should not be too strict in order to avoid the risk of finding too few patients. There is **no ideal number** of patient representatives. How many patients should be involved in the research process depends, among other things, on the available resources (financial means, time, and personnel) and the planned method of involvement. Diversity of expertise should also be considered when selecting patient representatives. In addition, special care should be taken when involving vulnerable patient groups.

How to find the right people to involve in clinical research

Currently, there is **no one-stop shop** for finding the right people to involve in a research project. Together with its partner organisations, the SCTO is planning a future **Swiss PPI Hub** and has started activities to facilitate the exchange between researchers and both patients and the public. For the time being, however, the SCTO recommends the following approach:

- Develop information material that clearly explains the involvement you are looking for and describes your research project in lay language.
- Identify and contact relevant patient organisations and ask how they can support your project/initiative.
- Post a call for interest on your website and/or your social media channels.
- Contact EUPATI CH[10] and ask for support within the EUPATI network: secretariat@eupati.ch.eu.

More information on PPI

If you have any additional questions about PPI, please contact Cordula Landgraf at the SCTO: c.landgraf@scto.ch.

[5] Visit the SNSF's website for more information: http://www.snf.ch/en/funding/programmes/iict/Pages/default.aspx#How%20To.
[6] See the Cancer Research UK's website: https://www.cancerresearchuk.org/funding-for-researchers/patient-involvement-toolkit-for-researchers/planning-your-patient-involvement/choosing-your-patient-involvement-method, accessed 29 March 2021.
[7] See the Patient Engagement Roadmap on EUPATI's website: https://eupati.eu/patient-engagement-roadmap/?lang=de.
[8] See the recommendation on PPI published in August 2020 by the Institute of Public Health and Nursing Research at the University of Bremen (in German): Handreichung zur Patient*innenbeteiligung an klinischer Forschung, Universität Bremen, Version 1.0.
[9] See A Researcher's Guide to Patient and Public Involvement, commissioned by the Oxford Biomedical Research Centre: https://oxfordbrc.nihr.ac.uk/wp-content/uploads/2017/03/A-Researchers-Guide-to-PPI.pdf.
[10] Visit EUPATI's website for more information: https://ch.eupati.eu/.

Figure 1: Possibilities for PPI

Identification of research questions (1)

Patients and the public can:

- identify relevant research questions or unmet medical needs
- help prioritise research questions
- establish contact with target patient group(s)
- …

Study design and funding application (2)

Patients and the public can:

- propose outcome measures/study endpoints that matter most to patients
- support the development of methods that are appropriate for patients
- improve the recruitment strategy
- …

Management and study process (3)

Patients and the public can:

- provide advisory support during the whole study project
- help develop patient information and other material, e.g. general consent forms
- …

Data analysis (4)

Patients and the public can

- check whether their interpretation of the data matches that of the researchers
- help identify potential research topics for future studies
- …

Dissemination and implementation (5)

Patients and the public can:

- help communicate the results of a study in lay language
- identify who benefits from study results
- support communication to a wider audience
- …

Evaluation (6)

Patients and the public can:

- help evaluate the impact of patient involvement
- provide relevant knowledge for future research projects
- …