

DCR–CTU Lecture

# Patient and Public Involvement (PPI) in Clinical Research

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### Agenda

- PPI Basics
- Case Study
- DCR PPI Support
- Message from two Patient Contributors
- Questions

# What is Patient and Public Involvement PPI? (I)

PPI (Patient and Public Involvement) in clinical research refers to **research conducted with or by patients and members of the public** (rather than 'to', 'about', or 'for' them) (INVOLVE, n.d.).

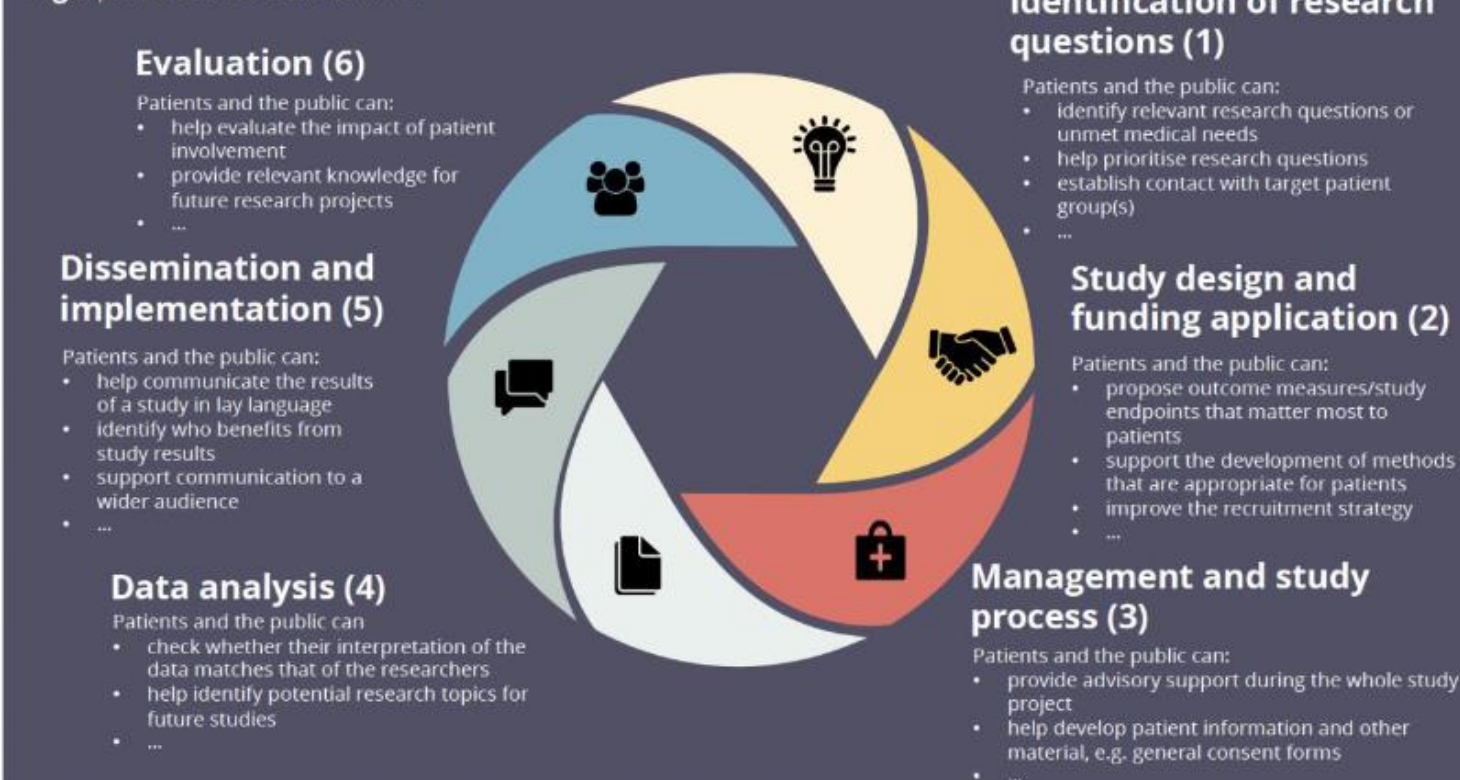
Patient representatives\* actively participate in shaping the goals, design, execution and evaluation of research projects, thereby differentiating PPI from simple participation in a research project (SCTO, n.d.).

\*The term "patient representatives" will be used for patients and members of the public. This includes patients, people who use health and social care services, family members, caregivers, patient organizations, patient experts, patient advocates, as well as the general public, including healthy individuals (SCTO, 2021).

- *INVOLVE definition of public involvement. (n.d.). <https://www.invo.org.uk>*
- *Swiss Clinical Trials Organization. (n.d.). SCTO Remuneration Policy for Patient and Public Involvement (PPI) Activities. <https://www.scto.ch/en/patient-and-public-involvement/ppi-resources.html>*
- *Swiss Clinical Trials Organization. (2021). PPI Guide for Researchers. <https://www.scto.ch/en/patient-and-public-involvement/ppi-resources.html>*

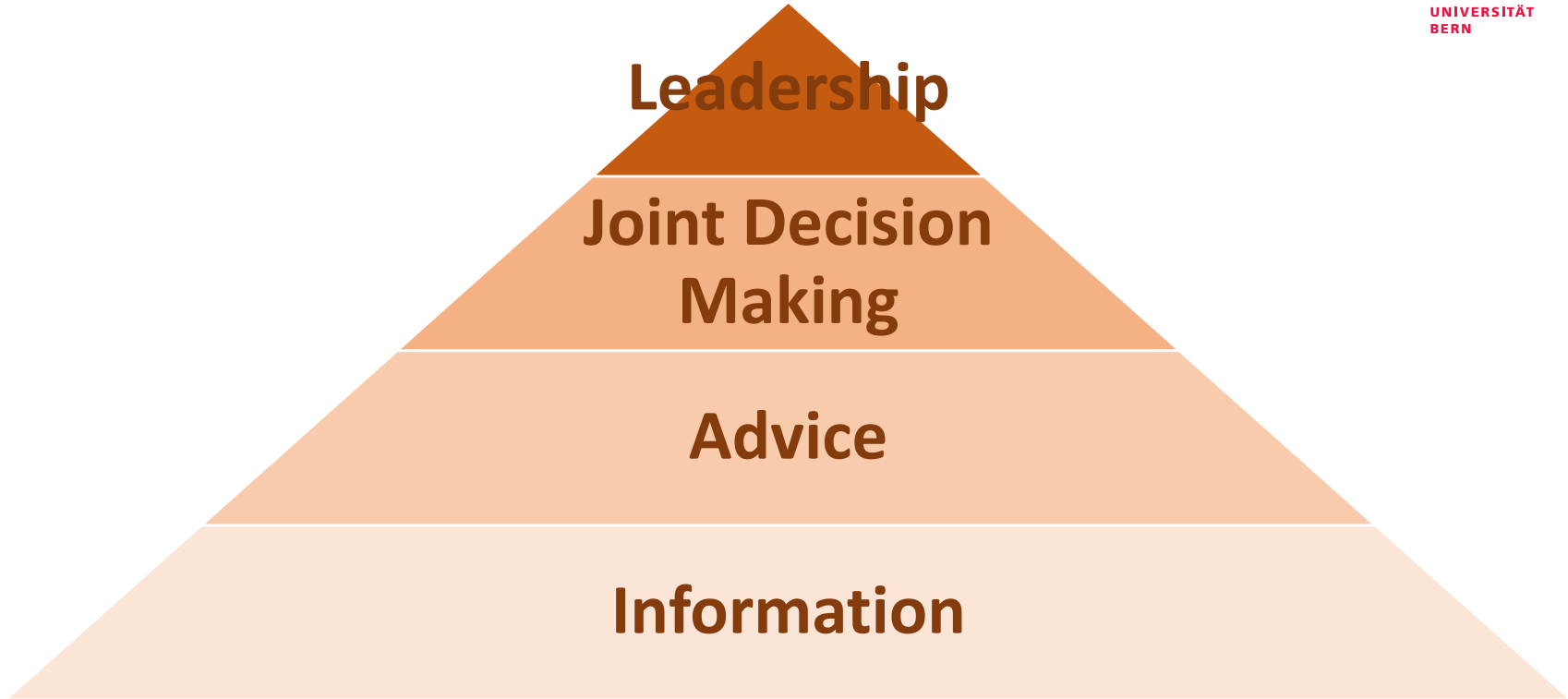
# PPI throughout the Research Process

Figure 1: Possibilities for PPI



Graph of the research cycle illustrating the different stages of a research project, and examples of how they can be involved. Swiss Clinical Trials Organization (SCTO) (2021). <https://www.scto.ch/en/patient-and-public-involvement/ppi-resources.html>

# Level of Involvement



# Terminology Patient Representatives

- **Individual Patients:** Persons with personal experience of living with a disease, contributing their experience and expertise.
- **Carers:** Individuals providing support to patients, including family members and helpers
- **Patient Advocates:** Individuals experienced in supporting a larger population of patients with a specific disease, affiliated or unaffiliated with an organization.
- **Patient Organization Representatives:** Individuals mandated to represent and express collective views of a patient organization on a specific issue or disease area.
- **Patient Experts:** Individuals with disease-specific expertise and technical knowledge in R&D and/or regulatory affairs, including EUPATI\* Fellows trained by EUPATI on medicines R&D.

\*The European Patients' Academy (EUPATI) is a pan-European project focusing on education and training to increase patients' ability to understand and contribute to medicines research and development,

# Why PPI?



PPI leading to research of greater quality, efficiency and relevance to the healthcare system, when addressing the needs of those affected. > It can enhance recruitment and retention in studies (Crocker et al., 2018; Domecq et al., 2024).



PPI corresponds to ethical considerations as patient representatives should be actively involved in clinical research, given that they are affected by research or pay for it.



Researchers are increasingly required to include PPI activities in research planning and implementation, e.g. Swiss National Science Foundation (SNSF) IICT funding program

Crocker et al. (2018). *Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis*. *BMJ*. <https://doi.org/10.1136/bmj.k4738>

Domecq J.P. et al (2014) *Patient engagement in research: a systematic review*, *BMC Health Services Research* 2014, 14:89  
<https://www.biomedcentral.com/1472-6963/14/89>

## Early Life Intervention in Pediatrics Supported by E-Health – ELIPSE

What? Mobile app based intervention

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Aims? To change parental behaviour to improve offspring health outcomes related to obesity and wheezing (by parental smoking)

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Who? Interdisciplinary approach between University for Psychiatry (UPD) and Pediatric Endocrinology, funded by Department for Education and Research, Bern

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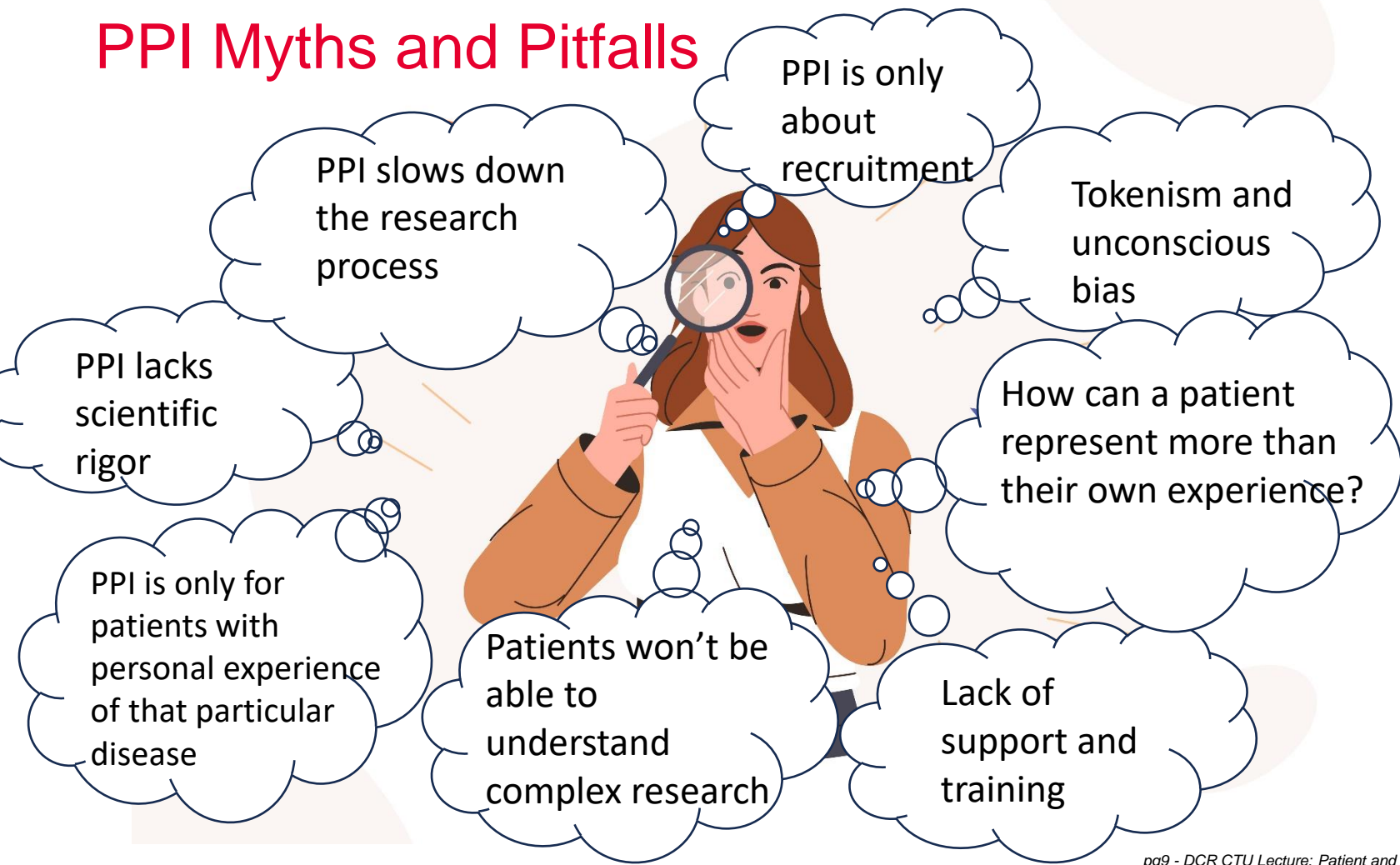
When? Ethics submitted  
First family in November 2023

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PPI Direct inputs by parents to guide app development, its usability, time of engagement, methods of motivation. To test first app drafts, to summarize study outcomes



# PPI Myths and Pitfalls



PPI slows down the research process

PPI is only about recruitment

Tokenism and unconscious bias

PPI lacks scientific rigor

How can a patient represent more than their own experience?

PPI is only for patients with personal experience of that particular disease

Patients won't be able to understand complex research

Lack of support and training

# PPI Challenges

- Education: PPI participants, researchers, rest of community
- Time
- Cost
- Attitude.....

**vs. BENEFITS**



# How does the DCR support PPI implementation?

Consulting and supporting Investigators to integrate PPI in their research projects

Support in identifying suitable PPI activities and methods for each phase of the research project.

Assistance in developing a project-specific PPI plan based on our DCR PPI plan templates.

## Template

### for the Patient and Public Involvement (PPI) section in the Proposal for the Swiss National Science Foundation (SNF) Investigator Initiated Clinical Trials (IICT) program

This adaptable template can be used for the Patient and Public Involvement plan in section 21 for the Proposal for the SNF IICT call. Use the template to describe how patients and the public have been involved in developing the research project to date and how patients and the public will be involved in the conduct / management of the research.

The costs associated with patient and public involvement can be entered in the requested funding on [mySNF](#) under the cost category "Patient and Public [Involvement](#)"

Phase	Activity	What is the role of the PPI contributor(s)?	What is the objective?
Management and study process	Involvement in training of investigators and other study staff regarding PPI in general and how to approach patients for recruitment; production and review of training materials;	Provide patient perspective and advice on training materials for study staff, <a href="#">co-author</a> and test training materials for study participants	Ensure study recruitment and conduct is patient-focused, understandable and optimizes patient and carer experiences throughout study

# How does the DCR support PPI implementation?

Establishing a DCR Patient Panel  
(Patient:innen Gremium).

Trained patient representatives for consultation regarding clinical research, improving patient and public understanding of clinical trials, positively influencing the public's knowledge and attitudes towards research.

A service available to researchers to form a project-specific panel: DCR panel members complemented with patients with lived experience, recruited by Investigator.



# How does the DCR support PPI implementation?

Providing training for both patient representatives and researchers

Online Training sessions provided by DCR

- For Patient Representatives: Basics of Clinical Research, PPI fundamentals, Role of Patient Representatives
- For Researchers: PPI fundamentals, Role of Patient Representatives

EUPATI Training: Extensive training for Patient Experts, contribution on Level Advise, Joint Decision Making



The screenshot shows a web browser window titled "Trainingsession für Patientinnen und Patienten". Below the title are two tabs: "Info" and "Druckansicht". The main content area has a blue header with the text "Herzlich Willkommen zum Trainingsmodul 'Was sind klinische Studien?'". Below this, there are three paragraphs of text. The first paragraph says "Dieser Kurs enthält Texte zum Lesen, Videosequenzen und Grafiken." The second paragraph says "Klicken Sie jeweils auf die Seitentitel in der blauen Zeile oben rechts oder links (z.B. 'Kursinhalte'), um nach vorne oder zurück zu gehen". The third paragraph says "Einige Wörter im Text sind rot geschrieben und unterstrichen. Diese Wörter werden im Glossar erklärt. Sie können auf die Wörter klicken, und gelangen so direkt zum Glossar." Below the text is a small image of a clipboard with a stethoscope. The fourth paragraph says "Während des Kurses können Sie Ihr Wissen mit Quiz prüfen."

Example for a training session: [Trainingsmodul "Was sind klinische Studien?"](#)

# Message from a Patient Panel Member



The screenshot shows a video player interface. The title is "Snapshot of AGITG CAP activities". To the right of the title is a small video thumbnail showing a woman speaking. Below the title, there is a list of bullet points, which are mostly illegible due to blurring. The video player has a green progress bar at the bottom.

Thank you Jane Mumford! The entire video can be accessed via: [Consumer Presentation v4 4 Eva - YouTube](#)

# Message from a Patient Panel Member



# We are eager to hear your questions!

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