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Public and Patient Involvement and Engagement in Europe and Switzerland

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Agenda

Patient and Public Involvement (PPI) in Clinical Research

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Patient and Public Involvement (PPI) in Clinical Research

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Patient and Public Involvement (PPI) in Clinical Research

- active collaboration of patients and public in shaping research
- address needs, priorities and perspectives of patients

https://imaginespor.com/our-patient-research-partners/

Implementation of PPI in Clinical Research

Range from passive involvement (information sharing) to active leadership (patient-driven research)

Different forms can be combined based on research phase and goals.

Forms of PPI:

- **Information** about research in plain language (e.g., brochures, public events)
  - → Transparency, raising awareness
- **Consultation** of patients to get feedback on specific aspects (e.g., surveys, focus groups).
  - → Align research with patient needs
- Patients as **partners** (e.g., advisory boards, co-designing studies).
  - → Ensure relevance and feasibility of research

Advanced PPI Forms in Clinical Research

Patient Empowerment

- Equal partnership with researchers, sharing leadership roles (e.g., co-authoring papers).
- Patient-Driven Research: Fully initiated and led by patients/organizations
  → Focus on patient-prioritized topics (e.g., rare diseases)
- Advocacy and Representation: Patients influence systemic decisions (e.g., ethics boards, policy development).
  → Amplify patient perspectives

Public Engagement

Additional PPI activities with the general public:

Educating and encouraging participation (e.g., science festivals, citizen science) leads to increase of transparency and societal support for research.

Feedback mechanisms:

- Patients evaluate research or provide input on their experience (e.g., post-study evaluations).
- Improve future PPI processes and ensure patient-centric outcomes.

PPI Initiatives in Europe and Switzerland

Key Regulations and Frameworks in Europe

Declaration of Helsinki (2024): **subjects → participants**

- respecting participants' autonomy and involving them in decision-making.

Good Clinical Practice R3 (ICH Guidelines):

- transparency and collaboration with patients during clinical research.
- patient-centered approaches in trial planning and conduct.

EU Clinical Trials Regulation (Regulation (EU) No 536/2014):

- Encourages patient involvement in trial design and public dissemination of results.

General Data Protection Regulation (GDPR):

- Protects participant data privacy, emphasizes informed consent for its use

PPI in Europe

EU supportive policies and programs:

- Horizon Europe: Mandates PPI in funded research.
- European Medicines Agency (EMA): Encourages patient input in regulatory processes.
- Innovative Health Initiative (IHI): EU public-private partnership, fund e.g., PARADIGM.
- European Patient Forum (EPF & EUPATI): Provide training and promote PPI

National Framework strategies and initiatives :

- UK: NIHR integrates PPI into funding criteria (e.g., INVOLVE).
- Scandinavian Countries: Integrate PPI via public health systems.

PPI in Europe - Patients Active in Research and Dialogues for an Improved Generation of Medicines

PARADIGM
Patients Active in Research and Dialogues for an Improved Generation of Medicines

Aim: to co-create solutions for meaningful PPI in development of medicines

Collaborative private-public framework

patients, pharmaceutical companies, healthcare professionals, and regulators.

standardized tools: patient engagement templates, guidance documents, metrics for PPI

Addressed barriers to participation, e.g., lack of training/unclear roles, ensuring that patients could actively and confidently contribute

Strengthened regulatory and ethical practices by incorporating the patient voice, enhancing transparency and trust in the medicines development process.

benchmark for structured and inclusive PPI in Europe

positive influence on relevance, quality, and acceptance of healthcare research and innovation

PPI in Europe –
James Lind Alliance Priority Setting Partnership (UK)

James Lind Alliance
Priority Setting Partnerships

Leading example of successful PPI in Clinical Research in Type 1 Diabetes

Identify research priorities in Type 1 diabetes based on input from patients, caregivers, clinicians.
Process: **surveys, workshops, and discussions**, giving equal voice to all stakeholders.
Outcomes: **"Top 10" research priority list** (e.g., improving blood sugar control, psychosocial impacts) with direct influence on funding and research agendas.
→ Ensure relevance of research to patient needs; foster trust and collaboration for future projects.

Funded by the National Institute for Health and Care Research (NIHR),

PPI in Switzerland

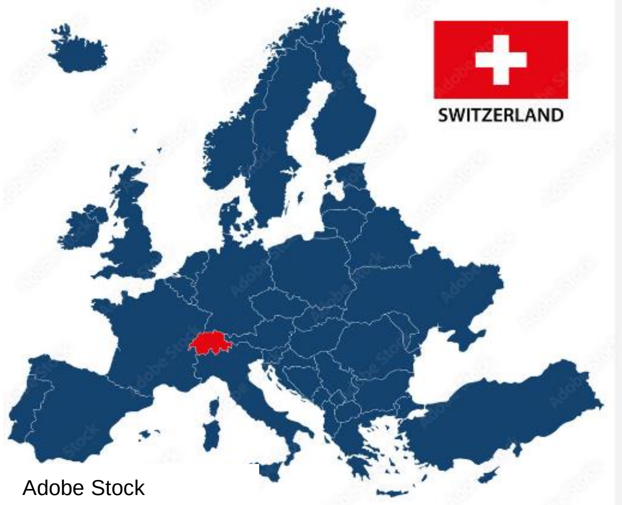
Less formalized than in Europe, but growing.

Key Organizations and Initiatives:

- Swiss Clinical Trial Organization (SCTO): Offers guidelines, workshops, and tools.
- Swiss Personalized Health Network (SPHN): patient perspectives in data use.
- Swiss National Science Foundation: Mandates PPI in selected research programs.

Challenges in Switzerland:

- Lack of standardized national PPI guidelines and/or regulations.
- Cultural and linguistic diversity complicates integration.
- Limited awareness.

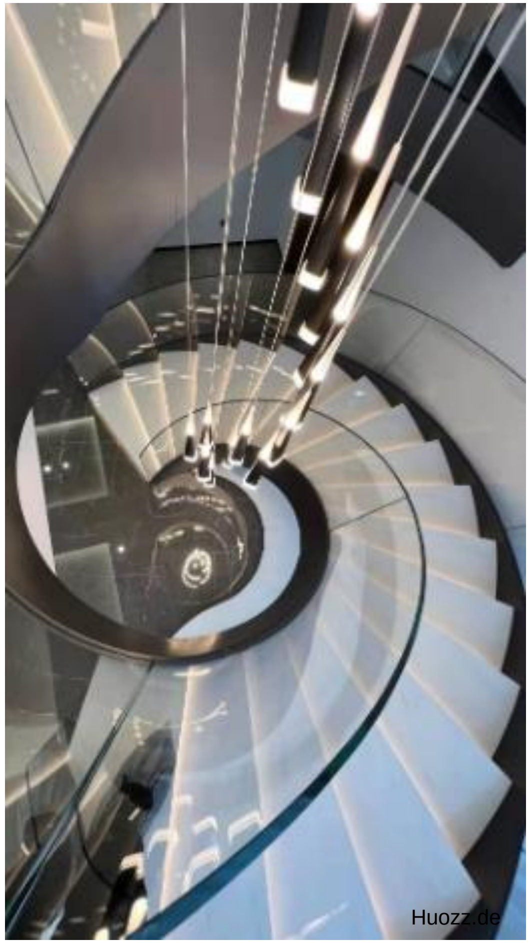


Adobe Stock

Impact and Challenges of PPI

Impact of PPI in Clinical Research

Involving patients ensures research projects address patient priorities, needs and concerns
-> **societal relevance** ↑


Huozz.de

PPI ensures patient-centered research -> **quality and feasibility** ↑

- effective recruitment strategies
- Tailored study schedule - reduces participant dropouts.

Enhanced communication using plain language -> **credibility and transparency** ↑

- builds trust with the public
- ensures ethical research practices
- clearer dissemination of findings

Challenges in Patient and Public Involvement (PPI)

Lack of acceptance and appreciation of patient contributions.

High time investment, limited funding and resources for PPI activities.

Unclear roles and power imbalances in decision-making.

Insufficient training for researchers and patients.

Barriers in understanding research processes and terminology.

Limited diversity in patient representation, barriers for marginalized groups

Requirements for successful PPI

Cultural Change and Awareness
Foster appreciation for patient expertise as equal to researchers.
Promote open and respectful communication.

Adequate Resources and Support
Allocate funding for PPI activities (honoraria, travel, childcare).
Offer logistical support (tools, materials, coordinators).

Trainingmag.com

Training and Capacity Building
Provide training for researchers in patient-centered methods.
Educate patients on research processes and medical terminology.
Facilitate joint training to enhance collaboration.

Structured Processes and Guidelines
Develop clear standards for integrating PPI (e.g., INVOLVE, PARADIGM).
Make PPI a core requirement in research funding

Conclusions

Conclusions

PPI is essential for patient-centered research.

PPI enhances transparency, relevance, and societal acceptance of research.

Broad spectrum of implementation: From passive (listeners) to active (initiators).

Standardization and resource development needed:

- Harmonized PPI standards across member states / worldwide (e.g., ICN PPI WG)
- Training options and resources for patients and researchers
- Raise researcher awareness of PPI benefits.
- Integrate PPI into funding programs by default.

Thank you for your attention

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