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An approach to implementing patient and public involvement in investigator-initiated clinical trials

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Summary

As patient and public involvement (PPI) in academic clinical research, especially clinical trials, is gaining recognition, including acceptance and implementation, questions arise about how to establish an effective "basic framework for PPI in academic clinical research" for all stakeholders in Switzerland. In this Viewpoint, the authors focus on one aspect of the survey and interview results reported by Eberle and colleagues from PPI contributors, researchers, academic research infrastructure staff, and representatives of regulatory and funding bodies to identify a possible direction for a basic PPI framework in Switzerland. Specifically, they describe how they prepare two groups of stakeholders – clinical researchers and PPI contributors – for collaboration. They present clear definitional distinctions to help clinical researchers prepare for the 2025 call for proposals from the Swiss National Science Foundation (SNSF) for Investigator-Initiated Clinical Trials (IICT) and provide important background information that is essential for understanding the fundamentals of PPI.

In 2024, Eberle and colleagues conducted a stakeholder analysis surveying 123 PPI stakeholders – patients and members of the public and researchers – in Switzerland and including 3 semi-structured interviews with representatives from the Swiss Clinical Trial Organisation (SCTO), Swiss National Science Foundation (SNSF), and Zurich cantonal ethics committee. Within the context of their mixed-methods study, they noted that "the main goal of implementing PPI for Patients and Public as well for Researchers was to foster the conduct of patient-relevant research" [1]. However, designing patient-relevant research – as Eberle and collaborators point out – requires awareness of PPI by all PPI stakeholders. We concur and consider PPI awareness the prime motivation for our present Viewpoint.

In our Viewpoint, we focus on one aspect of the findings reported by Eberle and colleagues regarding PPI contributors, researchers, staff members of academic research infrastructure, and regulatory and funding body representatives. We offer a possible direction for a basic framework for initiating PPI in Switzerland. Specifically, we describe how we prepare 2 groups of stakeholders – clinical researchers and PPI contributors – to partner together. We present clear definitions to assist clinical researchers in preparing for the 2025 SNSF Investigator-Initiated Clinical Trial (IICT) [2] call and provide important fundamental information that is integral for understanding PPI.

Defining PPI in clinical research in Switzerland

A simple act – explicit informed consent – produces a clear distinction and easily defines the difference between a PPI contributor and a research participant. PPI contributors are patients and their families and carers and/or members of the public. A patient is a person receiving medical care with specific experiential knowledge or lived experiences of diseases, conditions, and treatments. A member of the public is a person unrelated to the health care system. If a person provides their explicit, written informed consent to participate in a research project, they are a research participant. A patient can be a research participant or a PPI contributor; however, PPI contributors are not research participants (cf [1]). In table 1, we provide PPI terminology and definitions.

In the U.K.'s National Institute for Health and Care Research definition, PPI is widely recognised as "research that is carried out *with* or *by* patients or members of the public, instead of *to*, *about*, or *for* them" [3]. Depending on training and other competencies, PPI contributors partner, advise, and even lead aspects of clinical research. In Switzerland, PPI has been a required component of IICTs since 2018, with preparatory funding for PPI up to CHF

Table 1:
Department of Clinical Research (DCR) Bern patient and public involvement terminology.

Term	Definition
Patient and public involvement	Research that is carried out *with* or *by* patients or members of the public instead of *to*, *about*, or *for* them [3]
Patient and public involvement contributor	Patients and their families and carers and/or members of the public
Patient	A person receiving medical care with specific experiential knowledge or lived experiences of diseases, conditions, and treatments
Member of the public	A person unrelated to the health care system
Research participant	A person who provides their explicit, written informed consent to participate in a research project

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5000 available for successful IICT letter of intent applicants since 2022 [4–5]. The SNSF IICT PPI preparatory grant aims to help investigators fund PPI activities between July and October before full proposal submission in November [4]. However, outside the SNSF IICT call and its current requirement for PPI, other grants within Switzerland do not require PPI, even if a clinical trial is proposed.

Preparing investigators and contributors for PPI

The PPI Program in the Department of Clinical Research (DCR) at the University of Bern has been providing guidance to clinical researchers at Bern University Hospital, Inselspital, since 2023. In one-on-one PPI consultations, we endeavour to establish rapport with investigators and provide an essential foundation for understanding PPI in clinical research. In the DCR's conceptualisation of PPI, we categorically and wholly exclude current research participants as PPI contributors. Although qualitative approaches, such as focus group interviews, are used systematically to provide room for PPI contributor influence, PPI itself is not research. We also prioritise the second "P" in PPI – members of the public – whereas more specialist organisations, such as the Swiss Group for Cancer Research (SAKK), which hosts a patient advisory board and patient expert training from the European Patient Academy on Therapeutic Innovation (EUPATI) [5] and its platform EUPATI Switzerland [6], provide training for patient experts.

At the DCR Bern, we recently designed and launched (March 2025) a post-graduate course, PPI for Clinicians [7]. The course focuses on understanding the foundations of PPI in clinical research with pre-requisites of Clinical Investigator I: Basic Good Clinical Practice and Clinical Research Training. We also strongly recommend completing Clinical Investigator II: Advanced Good Clinical Practice and Clinical Research Training. Although current swissethics Good Clinical Practice learning outcomes and learning content do not explicitly cover PPI in clinical research [8], we support investigators by offering guidance aligned with PPI, such as "Like Good Clinical Practice, documentation of PPI activities is essential for successful IICT applications" – a statement we share with investigators when we meet with them.

We anticipate that Good Clinical Practice training in Switzerland will eventually include PPI as a content area since the International Council on Harmonisation (ICH) E6 revision 3 (ICH E6 R3) [9] and the 10th revision of the Declaration of Helsinki [10] reference engaging communities. For example, ICH E6 R3 notes:

– The design and conduct of the clinical trial may be supported by obtaining the perspectives of interested parties, such as patients and their communities, patient advocacy groups and healthcare professionals. Their input can help to reduce unnecessary complexity, improve feasibility and increase the likelihood of meaningful trial outcomes. The use of innovative trial designs and technologies may enable the inclusion of a wider and more diverse population of participants and thereby broaden the applicability of trial outcomes. [9].

The Declaration of Helsinki includes the following statement:

– Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled participants and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating results. [10]

We also operate under the assumption that PPI contributors bring experiential knowledge with them and that their perspectives are important for clinical research. However, PPI contributors also require basic knowledge about clinical research processes and requirements to effectively function as PPI contributors. Whether patients, members of the public, or patient experts, PPI contributors receive an online, asynchronous four-module training describing (1) clinical trials; (2) legal and ethical human research principles; (3) the clinical trial process; and (4) how patients and the public can participate in clinical research. We refer to our PPI training as Good Clinical Practice light – although not entirely accurate, it demonstrates to investigators a tacit relationship between Good Clinical Practice and PPI and our approach to training PPI contributors.

We provide an overview of our recommendations for PPI in table 2.

Understanding the DCR Bern's standing PPI panel approach

As part of DCR's support for clinical researchers, our PPI Program includes a standing PPI contributor panel of 45 trained individuals with various roles, namely, patients, patient experts, and members of the public, which we formed in 2023. When investigators ideally meet with us prior to submitting letters of intent for the SNSF IICT call, we recommend an approach that includes forming a study-specific panel of PPI contributors from a mix of patients – not study participants – that they identify for their lived experience of the studied disease, condition and/or treatment and a handful of PPI contributors from our standing panel. We advise a mix because naïve PPI contributors – members of the public – also offer unique insights along with patients, their families, and carers. All members of the study-specific panel complete our four-module PPI training.

If investigators are awarded the PPI preparatory grant, PPI contributors meet with investigators and their teams during study-specific panel meetings. PPI contributors are remunerated for their time [13]. We recommend that PPI contributors be compensated at least CHF 60 per hour for their work. If a PPI contributor is a patient expert, we recommend higher remuneration between CHF 100–120 per hour. Although not comprehensive, at this stage, PPI contributors can offer advice, experience, feedback, and guidance on:

– Lay study summaries
– Study design
– Research questions
– Endpoints and quality of life measures
– Recruitment and retention strategies

Table 2:
Department of Clinical Research (DCR) Bern patient and public involvement (PPI) recommendations.

PPI recommendations	Rationale	Resources
1. Prepare investigators and contributors for PPI with sufficient training aligned with their roles in IICTs.	In Switzerland, PPI is relatively new. To help investigators and PPI contributors partner and collaborate, offer training to prepare each stakeholder for researcher-PPI contributor partnerships.	PPI for Clinicians course at DCR Bern [7]
2. Continue to provide training for investigators, research teams, and PPI contributors as needed from pre- submission until the IICT ends.		Swiss Clinical Trial Organisation online PPI Course for SNSF IICT Grant Applicants [4]
		EUPATI [5] or EUPATI Switzerland [5] training for patient experts
3. Consider adding PPI-related learning objectives to Good Clinical Practice curriculum in Switzerland at investigator and investigator-sponsor levels, then also provide PPI updates in Good Clinical Practice Refresher courses.	PPI in IICTs continues to gain traction in Switzerland. Since Good Clinical Practice for investigators and investigator-sponsors is needed, Good Clinical Practice content related to PPI can provide investigators with additional knowledge for promoting effective researcher-PPI contributor partnerships.	swissethics Good Clinical Practice requirements for investigator courses [6]
4. Budget to remunerate PPI contributors – members of the public, patients, and patient experts – commensurate with their experiential knowledge; basic knowledge about clinical research processes and requirements; and relevant training (either bespoke or from EUPATI).	PPI contributors offer their experiential knowledge to improve IICTs. However, they oftentimes require additional training to perform PPI activities and tasks when conducting trials. PPI contributors should be compensated appropriately based on their training, knowledge, and involvement.	SCTO Remuneration Policy for PPI Activities [13] (PDF)
5. Systematically budget for, plan, and document PPI activities and PPI contributor involvement for the entire duration; create an agreement for PPI contributors to define the scope of their involvement.	As a matter of Good Clinical Practice, document all PPI activities. Furthermore, use the documentation to assess PPI in the IICT, as well as report PPI in research reports about the IICT.	SCTO Planning, Tracking, and Evaluating PPI Activities Template [15] (xlsx)
		EUPATI Patient Engagement Agreements Explained [16]
		GRIPP2 PPI Reporting Checklist [9]
6. Leave room for PPI contributor influence when planning PPI activities, post-award.	SNSF requires feedback from PPI contributors on the IICT lay summary, research questions, endpoints, and recruitment for the full proposal submission in November. Instead of creating fully developed PPI plans for IICTs in the full November submission, provide space for PPI contributors to co-create and provide their influence by building a framework for PPI contributors to offer their input.	swissethics Swiss specific addendum to Clinical Trials Ordinance, ClinO: Transparency and requirement of a lay summary in BASEC [12] (PDF, p. 4)
		swissethics Lay summaries of Clinical Trial Results: Ethical Considerations from swissethics [17] (PDF)
		Plain language ISO [18] (PDF; paywall)

IICT: investigator-initiated clinical trials; PPI: patient and public involvement; SCTO: Swiss Clinical Trial Organisation; EUPATI: European Patients' Academy on Therapeutic Innovation; ISO: International Organisation for Standardisation; BASEC: Business Administration System of Ethics Committees; SAKK: Swiss Group for Cancer Research; SNSF: Swiss National Science Foundation.

Each PPI contributor on a study-specific panel can have different roles or levels of involvement; however, we strongly urge that PPI contributors are sufficiently trained for their level of involvement. For example, even though PPI contributor motivation, availability, and expertise levels might suggest a particular level of involvement, we recommend roles beyond providing advice as suitable only for individuals who have completed EUPATI or EUPATI Switzerland training for patient experts or bespoke training appropriately designed for PPI contributors. We suggest partnering with clinical trial units, centres of clinical research, or DCR Bern to develop the training.

Reflecting on PPI at the DCR Bern

Since 2023, when DCR began offering PPI guidance for investigators, we have learned important lessons. First, budgeting for PPI activities is an art and a science. The art of budgeting for PPI activities includes carefully considering the various aspects of study design where investigators can create space for the influence of PPI contributors to shape the study. It also includes providing opportunities for investigators to create, maintain, and sustain successful partnerships throughout the entirety of the IICT study cycle, from prioritising, shaping, designing, conducting, and interpreting to reporting, implementing, communicating, and evaluating. The science of budgeting requires recognising that PPI contributors have other roles and responsibilities that require their time and attention. In turn, their remuneration should be commensurate with their level of involvement and subsequent PPI contributor training, including any planned and budgeted uptraining they complete during the IICT.

Second, sufficient training on PPI is essential for the successful uptake of PPI initiatives across Switzerland for investigators and PPI contributors alike, as well as for administrative and research staff involved in clinical trials. Our PPI Program has sought to provide sufficient training for PPI contributors and investigators – the former in 4 module trainings and the latter through in-person consultations and the PPI for Clinicians course. We also identified an absence of PPI in the medical school curriculum. In response, we offer Clinical Trials in Action, a week-long course for medical students to experience various facets of clinical trials, including PPI consultations, along with investigators.

Finally, PPI is relevant for translational and even basic research for the same reasons it is relevant for clinical research. PPI offers benefits for both interventional and observational clinical research when researchers and PPI contributors partner. We hope that PPI requirements are eventually extended across all publicly funded research in Switzerland. Specifically, we advocate for a similar preparatory grant to support researchers and their teams for easier PPI involvement and engagement before full proposal submissions. For example, similar to the Swiss National Science Foundation (SNSF) and the philanthropic Rising Tide Foundation for Clinical Cancer Research based in Schaffhausen [14], other funders – public and philanthropic – in Switzerland might consider using pre-application or preparatory grants as a model for integrating PPI into calls for translational and even basic research.

Potential competing interests
All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of

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