DEEP DIVE

PPI IN SWITZERLAND: A REGULATORY PERSPECTIVE

REGULATORY ASPECTS OF PATIENT AND PUBLIC INVOLVEMENT IN ACADEMIC CLINICAL RESEARCH IN SWITZERLAND

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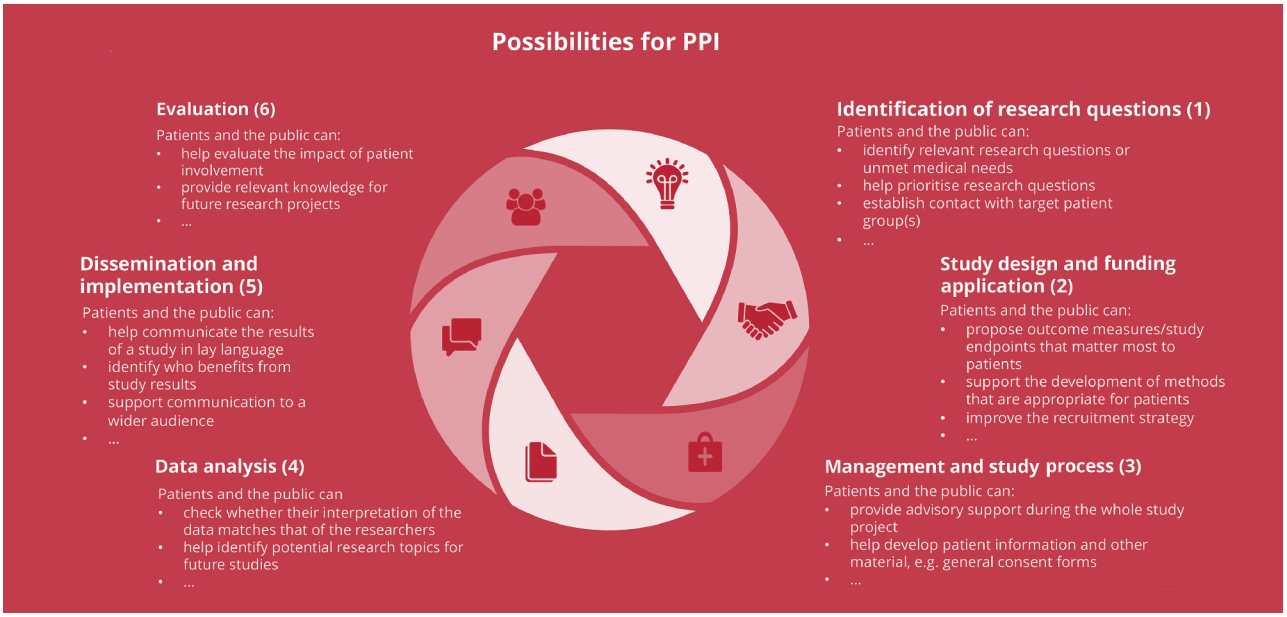
Patient and public involvement (**PPI**) describes the active engagement of patients and the public in different aspects of clinical research. This Deep Dive article covers the current situation of PPI in academic clinical research in Switzerland, giving examples of local support and initiatives that are currently offered by university hospital clinical trial units (**CTUs**) and also addressing the lack of legislation related to PPI. In addition, it provides an overview of data protection regulations to be considered when working with data generated during PPI and ends with a discussion of the key issues related to PPI in Switzerland.

WHAT IS PATIENT AND PUBLIC INVOLVEMENT IN CLINICAL RESEARCH?

PPI in clinical research – as defined by INVOLVE, the former advisory group of the National Institute for Health Research (**NIHR**) in the United Kingdom – is "research being carried out 'with' or 'by' patients and members of the public rather than 'to', 'about' or 'for' them". The overall aim of PPI is to make clinical research more relevant to patients. Patient representatives can take part in different activities throughout the research process, as illustrated in the PPI Guide for Researchers by the Swiss Clinical Trial Organisation (**SCTO**) (see **Figure 1** on the next page). For example, patient representatives can be involved in the identification of research questions or unmet medical needs and the prioritisation thereof by filling in a questionnaire. When designing a study or applying for funding, they can give input about study endpoints that reflect patients' priorities. These endpoints may be translated in studies as

patient-reported outcomes (**PROs**) or the measurement of outcomes (patient-reported outcome measures (**PROMs**)). With their knowledge based on personal experience, patient representatives can also offer advice on patient-friendly study design through interviews or focus groups. Patient representatives can also be involved in the study process and its management by being part of an advisory group. During the process of data analysis, patient representatives can provide insight into their interpretation of study results. When disseminating and implementing study results, patient representatives can play a crucial role by identifying the dissemination audience and strategies and by helping provide study results in lay language. In the evaluation stage, patient representatives can help to evaluate the impact of patient involvement and identify its strengths and weaknesses in order to guide future projects.

Figure 1: Possibilities for involving patients and the public in academic clinical research



Source: SCTO's PPI Guide for Researchers

LEGAL BASIS FOR PPI IN SWITZERLAND

In 2015, the Federal Council evaluated the participation rights of patient organisations and patient involvement in health policy processes as part of its Health2020 strategy (Swiss Confederation 2015). One goal of Health2020 was to "empower insurees and patients" while focusing on "increasing the health skills and individual responsibility of insurees and patients", which would lead to a promotion of patient involvement (see Objective 2.3, FOPH 2013). However, it was concluded that no federal law for a central information point about patient rights issues would be established due to the complicated nature of shared competences between the cantons and the federal government. This decision was affirmed after an interpellation in 2020 (Swiss Parliament 2020). Nevertheless, the promotion of health literacy remained an objective of the Federal Council in Health2030 in order to increase access to health literature and information and to support patients' decision-making in health-related issues (FOPH 2019). Examples of this support are initiatives such as the national license for the Cochrane Library and the information portal of the Swiss Red Cross (migesplus.ch). The Federal Council supports the involvement of patient organisations in health policy processes but has not expressed any intention to legally anchor this involvement (Swiss Confederation 2015).

Despite the lack of legislation related to PPI in Switzerland, PPI guidelines exist, for example the Pharma Cooperation Code for the pharmaceutical industry, which focuses on advisory activities of patient organisations and potential conflicts of interest. According to the code, these advisory activities are only allowed "if such consultancy tasks or services are provided to support healthcare or research and cannot be interpreted as an incentive to recommend, prescribe, acquire, deliver, sell or administer specific medicinal products". The Swiss Ordinance on Organisational Aspects of the Human Research Act (**OrgO-HRA**) sets forth considerations regarding the work processes of ethics committees, which may also include patient members.

PPI AND SWISS DATA PROTECTION LEGISLATION

As part of a political and legal basis for addressing PPI, data protection needs to be taken into account. Data generated in PPI processes are not typically covered by the Human Research Act (**HRA**) but may be protected by federal or cantonal data protection legislation. General data protection principles such as lawfulness, data minimisation, purpose limitation, transparency, accountability, integrity, accuracy, and data security need to be followed. The main considerations for determining which law is applicable and the extent to which it is applicable are firstly, whether the data is anonymised and therefore cannot be reidentified in any way and secondly, who processes the data (see **Figure 2**).

When processing personal data, private organisations must comply with the Federal Act on Data Protection (**FADP**), whereas cantonal institutions such as university hospitals must comply with their canton's data protection laws. According to the FADP, a data subject's consent is, as a rule, required for data processing within the scope of PPI. Cantonal data processors usually require a legal basis, which varies between cantons. When health data is processed, generally stricter requirements must be met, such as explicit consent or express authorisation for data processing in a law. Unlike personal data, anonymised data are not covered by any data protection legislation.

Figure 2: Overview of data protection in Switzerland as it relates to personal and anonymised data

Data \ Data processor		Cantonal institutions	Private organisations
Personal	Applicable data protection acts	Cantonal legislation on data protection	Federal Act on Data Protection (FADP)
	Basis for data processing	Statutory or consent, depending on cantonal laws	Consent
Anonymised		No applicable data protection legislation	

Sources: FADP (see Art. 3, let. a) and the glossary of the Federal Data Protection and Information Commissioner (in German)

PPI SUPPORT AND GUIDANCE FROM SWISS ACADEMIC CLINICAL RESEARCH

PPI in clinical research has increasingly attracted the interest of not only political stakeholders but also patients, patient organisations, research infrastructures, and funding bodies. There are individual initiatives for PPI, such as the Patient Advisory Board initiated by the Swiss Group for Clinical Cancer Research (**SAKK**) and the PPI Fact Sheet and PPI Guide for Researchers created by the Swiss Clinical Trial Organisation (**SCTO**) and endorsed by the Swiss National Science Foundation (**SNSF**). The SNSF includes PPI as one of its funding criteria for academic clinical trials and involves patient representatives in the evaluation of projects (see **SNSF** article on p. 14). In addition, many PPI initiatives exist at university hospitals and their CTUs. However, there is currently no national initiative to support, promote, or harmonise these individual initiatives. This is in contrast to other countries, such as Canada and the UK, that have established national initiatives.

The five university hospitals in Switzerland and their associated CTUs have launched several individual initiatives to guide, advise on, and promote PPI. For instance, the Department of Clinical Research (**DKF**) at the University of Basel has developed brief internal guidelines for PPI with references to further resources. The Clinical Trials Center (**CTC**) at the University Hospital Zurich (**USZ**) is planning to set up guidelines and as a first step has started a master's thesis project in order to get an overview. The DKF in Basel and Lausanne University Hospital (**CHUV**) also offer specific consulting services for researchers for including PPI in their projects. Other initiatives that have been launched to support PPI in clinical research include the CTU Bern's plans to establish a basic toolbox for PPI and its lectures on PPI. The DKF in Basel and the European Patients' Academy on Therapeutic Innovation Switzerland (**EUPATI CH**) are collaborating to establish training for patients on clinical research and patient engagement in Switzerland. Additionally, the DKF is planning discussions on how to integrate a patient panel into research activities. CHUV has organised a consultation involving parents and children to evaluate general consent documents for minors. Moreover, CHUV has organised several focus groups with CHUV patients to discuss research results disclosure. The CTC at the USZ is preparing to add patient-focused information to its website, including links to lay summaries. The USZ has also started a hospital-wide initiative to digitalise and harmonise PROMs. Further, an initial initiative to include patients in data entry into case report forms has been launched. Geneva University Hospitals (**HUG**) have the only university hospital initiative that unites all PPI resources, guidelines, and consulting in one project; this initiative is led by the Clinical Research Partnership Team (**PARTNER REC**) (see **CASE STUDY** on p. 33).

DISCUSSION OF KEY ISSUES

Individual PPI initiatives launched by university hospitals and their CTUs show different approaches and levels of development. Concurrently, a national PPI approach across organisations is being developed by the SCTO (see **INNOVATION CORNER** article on p. 36). A harmonised initiative at the federal level is lacking and there is no legal or regulatory framework in place specifically for PPI in Switzerland. Federal legislation or guidance could help promote and facilitate good practises, for example on managing competing interests and conflicts of interest when conducting patient engagement activities, and could help to clarify requirements for processing personal and health data generated in PPI processes.

Currently, the most relevant regulations to consider are data protection acts. In contrast to anonymised data, processing personal data requires at least obtaining individuals' consent to allow data processing by private processors. This consent is also sufficient for some cantonal processors. However, clarification is needed for data processing on a statutory basis, which is required by some cantons. This situation remains unclear and could be clarified by federal regulatory or legal guidance on PPI in Switzerland. For documentation and transparency reasons, patients should be informed about the purpose of PPI, the data to be collected, and how these data will be used, including potential publication. A written agreement describing PPI activities between patient representatives and researchers would be considered good practice.

CONCLUSION

PPI in academic clinical research aims to promote the empowerment of patients and increase the relevance of research to patients and the general public. While clinical research projects are regulated through the HRA and its related ordinances, a legal anchor for PPI is not currently in place – nor is one being planned – in Switzerland. A national initiative from the SCTO spanning different organisations and several individual initiatives is currently being undertaken to promote and support PPI in academic clinical research. Looking forward, a harmonised national approach to PPI that is supported by the federal government would further enable Switzerland to better reap the benefits of PPI in clinical research.

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