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# REGULATORY AFFAIRS WATCH

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## EDITORIAL



### BRINGING PATIENTS' AND THE PUBLIC'S VOICES INTO HUMAN HEALTH RESEARCH

This issue of *Regulatory Affairs Watch* gives us the opportunity to thank all study participants for their involvement in our human research projects. Without them, trials would simply not happen. Yet what is at stake when involving patients and public in clinical research goes far beyond their enrolment in trials. It is now widely recognised that patients' contributions help address areas and questions in research that are important and relevant for not only patients but also the public at large. Giving patients and the public a role in shaping clinical trials in terms of inclusion and exclusion criteria, design, and outcomes helps research teams to ensure a trial is feasible, practical to run, and relevant to patients (see **Box 1** on the next page for various profiles of PPI contributors). At the same time, the effects of potentially biased lobbying – for example the role the US Alzheimer's Association reportedly played in the recent [aducanumab FDA approval case](#) – should also be taken into consideration when promoting public involvement in clinical research. We can only hope that the involvement of patients in academic research will counterbalance such a drift.

Some countries are ahead in the field of patient engagement. Researchers in the UK, for instance, have been involving patients' perspectives in clinical research for more than 15 years. In Switzerland, a growing number of clinical research projects engage patients; however, patient and public involvement (PPI) has not yet been implemented equally at all stages of research projects.

Similarly, all research institutions are not at the same stage of development. This is partially explained by the fact that PPI requires both a political push and a shift in thinking in the minds of researchers. Such a change in the human health research paradigm should also be accompanied by consistent resource allocation, including compensation for the time dedicated by patients and the public. A greater effort to include PPI in academic clinical research will be rewarded because it will help to limit research waste and increase the impact of research on public health.

The PPI ball has started rolling in Switzerland – slowly but surely! In this issue of *RA Watch*, we illustrate where active Swiss stakeholders stand on this subject and how they are promoting PPI in clinical research.

- **DEEP DIVE:** Our first Deep Dive article takes a look at the Swiss PPI regulatory environment from a clinical research perspective. Our second Deep Dive article depicts PPI benchmarks and initiatives that exist in Europe and North America from a patient advocacy perspective.
- **NEWS FROM:** As the research funding organisation for the investigator-initiated clinical trials (IICT) programme in Switzerland, the Swiss National Science Foundation (SNSF) describes the role patient experts now play in the evaluation of clinical research applications. In addition, swissethics and Swissmedic describe their PPI initiatives.

- **VIEWS AND OPINIONS:** EUPATI CH discusses how it promotes PPI through its patient education programmes and provides details of the new Swiss training module it is currently developing. How do patient organisations view PPI? What are some of their PPI initiatives? What do they think is still missing? The patient organisation ProRaris addresses these questions and more in its article. And the Swiss Academy of Medical Sciences presents a summary of how to make clinical research in Switzerland more patient-centred from its recently published White Paper: Clinical Research.
- **CASE STUDIES:** Case studies from the field at Geneva University Hospitals and the University Hospital Basel provide excellent examples of PPI in clinical research and highlight its practical benefits.
- **INNOVATION CORNER:** And last but not least, the Swiss Clinical Trial Organisation (SCTO) presents its new national PPI project, which includes plans for a national PPI hub.

After reading this issue, we hope people involved in academic human research projects will all be motivated to see and evaluate their projects through the eyes of patients and the public.

On a personal note, at a time of many changes within the team of the SCTO's Regulatory Affairs Platform, I would like to take the opportunity to acknowledge the tremendous work and dedication that Séverine Méance provided in her role as RA Watch Editor – as she established this newsletter and helped it flourish. I also join the RA Platform's members in recognising and thanking successive RA Platform Coordinators Laure Vallotton, Séverine Méance, and Loane Warpelin-Decrausaz for the commitment and dedication they brought to this project. And finally, I would like to welcome and thank Isabelle Guilleret, who has taken over the RA Platform's coordination ad interim.

### Box 1: Various profiles of PPI contributors

**Individual patients:** People who have personally experienced living with a disease. They may not have technical knowledge of the R&D or regulatory processes but can contribute their personal experience with a disease and its treatments.

**Carers/caregivers:** People who support individual patients, for example family members, volunteer helpers, and paid assistants (with the exception of healthcare professionals).

**Patient advocates:** People who have in-depth knowledge of a specific disease and experience in supporting larger groups of people who live with a specific disease.

**Patient organisation representatives:** People with a mandate to represent and express the collective views of a patient organisation on a specific issue or disease area.

**Patient experts:** People with expertise on a specific disease and technical knowledge of the R&D and/or regulatory processes that has been acquired through training or experience.

Source: Adapted from Haerry et al.'s article from 17 August 2018 in *Frontiers in Medicine*: <https://doi.org/10.3389/fmed.2018.00230>



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## 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

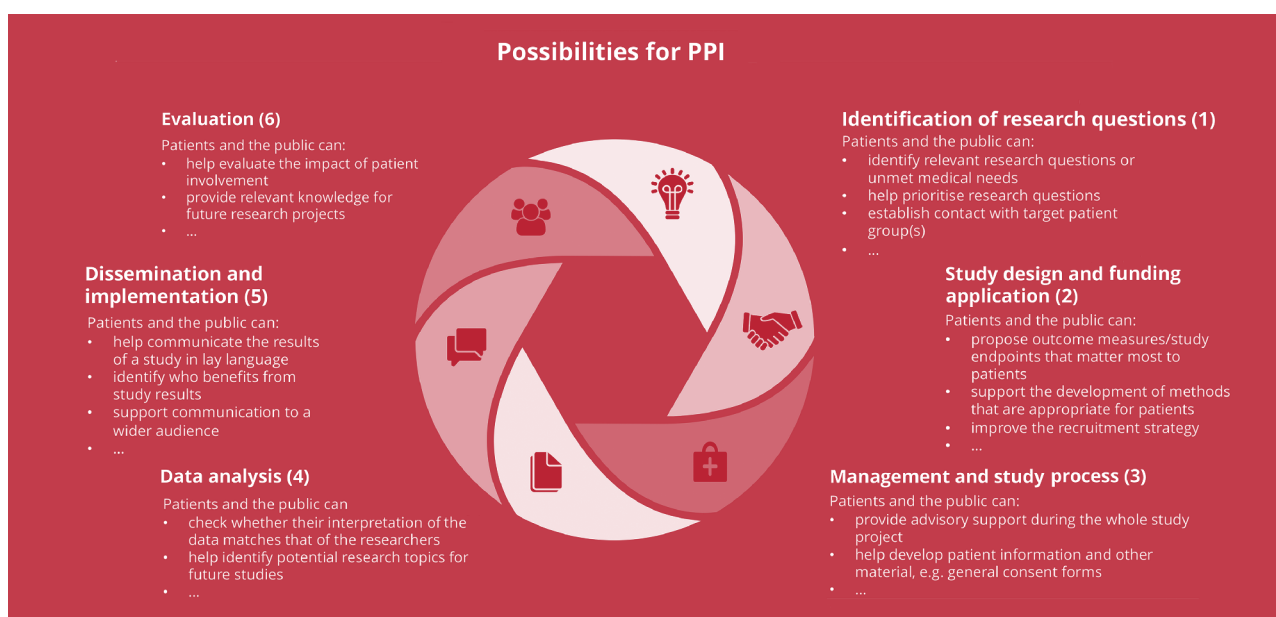
in the [PPI Guide for Researchers](#) by the Swiss Clinical Trial Organisation (SCTO) (see **Figure 1** on the next page). For example, patient representatives can be involved in the identification of research questions or unmet medical needs and the prioritisation thereof by filling in a questionnaire. 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 rep-

resentatives 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 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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## DEEP DIVE

### PPI ABROAD: A PATIENT ADVOCACY PERSPECTIVE



### THE EVOLVING PRACTICE OF PATIENT AND PUBLIC INVOLVEMENT IN EUROPE AND THE UNITED STATES

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Patient and public involvement (PPI) in academic human research has been evolving in the United States and Europe since the early 1980s, when it was jump-started by activists responding to the HIV pandemic. This article provides a brief look at the development of PPI in academic human research in the US and Europe, highlights the PPI initiatives of several US and European organisations, discusses how PPI is gaining momentum in health technology assessment bodies, and provides recommendations for various stakeholders on how to incorporate more PPI into academic human research.



## THE DEVELOPMENT OF PPI IN THE UNITED STATES AND EUROPE

Similar to health systems, the academic research environment was not originally planned around the patient. With the Declaration of Helsinki adopted only in 1964, we are still struggling to make patients' and society's needs the ultimate arbiter of what is *acceptable*, *reasonable*, and a *priority* for patients in academic human research. The change in the historical relationship between healthcare professionals and patients became evident during the HIV pandemic in the early 1980s, a time of increased political activism towards social acceptance. HIV activists used their existing advocacy know-how to successfully lobby public health authorities such as the US Food and Drug Administration (FDA). Activists' main argument was that the regulatory process should serve patients' interests and thus enable faster approvals and early access to life-saving medication. As a result of their efforts, the FDA started collaborating with patients in 1988 and, ultimately, promising HIV drugs were released on a parallel track before approval.

In Europe, it was again HIV patients in the 1990s knocking at the doors of the newly established European Medicines Agency (EMA) who inspired the regulator to adapt European legislation and lay the groundwork for involving patients in all its processes and decision-making. This activism established a precedent for collaboration with patients with all indications, accelerated approval processes, and introduced expanded access pathways.

Today, PPI is becoming increasingly integrated into academic human research. Stakeholders beyond medicine – including those in the areas of digital health and data, medical devices, and health systems – better understand

the value of patient involvement; however, fragmentation remains an obstacle to replicability, scaling, and adoption across health systems. This often results in a gap in patient-centred outcomes addressing unmet needs, in lower performance of healthcare stakeholders, and in increased costs to society. Improved patient involvement can drive the development of innovative medicines, devices, digital health, and care services that deliver more relevant and impactful patient outcomes. Patient involvement can also make medical product development faster, more efficient, and more productive. In addition, it leads to a better understanding of patients' needs, better prioritisation of early research, improved decision-making and resource allocation, and trial protocol design that better reflects patients' needs. Consequently, PPI lowers potential barriers to patient participation, enhances recruitment, and increases retention.

Historically, the US has been the main driver of PPI because of the FDA's active role in writing its own legislation. Recently, the UK has become a European leader in PPI in terms of its number and range of initiatives. And although generally, little legislation directly related to PPI exists in Europe, there are several examples of European and national guidance and initiatives as well as many initiatives from individual organisations (see **Box 1** at the end of this article for a selection of PPI legislation, guidance, and initiatives in Europe and North America). The following organisations demonstrate several of the efforts being made to achieve more patient involvement in academic human research in the US and Europe.

## A SELECTION OF ORGANISATIONS IN THE US AND EUROPE WITH PPI INITIATIVES

### US Food and Drug Administration (FDA)

Since 1988, the FDA has taken several measures to engage patients in its processes (see its summary [Evolution of Patient Engagement at the FDA](#)). It has shaped the most recent efforts to advance the patient voice in regulatory processes through the [Patient-Focused Drug Development Program](#) with the development of [four FDA guidances](#) articulating how stakeholders should collect and submit

input from patients to contribute to medicine development and regulatory processes. There is an increasing expectation that the FDA will make patient engagement mandatory in regulatory documents (e.g. patient experience data). This is only the beginning of a series of public health authority efforts to build better patient voices in development and decision making.

### European Medicines Agency (EMA)

At its creation in 1995, the EMA had no formal policy for talking to patients. Members of the European AIDS Treatment Group (EATG) approached the EMA in 1996 and asked the agency to accept running pivotal studies with biomarkers instead of clinical endpoints to shorten the time to approval. Regulators understood that patients had something important to say and agreed to meet and start discussions with them. The EATG was also the first to alert the EMA about worrying side effects observed in HIV patients under combination therapy in 1997 – an observation that resulted in regulators changing their pharmacovigilance strategy from reactive to proactive, especially in fast-track approved medicines.

From 2000 onwards, the EMA made patient representatives full members of its Committee for Orphan Medicinal Products (COMP). The agency realised it required legislation enabling further integration of patients in its processes. Regulation (EC) No. 726/2004 of the European Parliament and of the Council of the European Union, in particular Article 78(1), gives the EMA additional responsibility to

develop contact with patients and consumers. On this basis, the agency established its Patients' and Consumers' Working Party (PCWP), a platform for patients and consumers to exchange information and information with the EMA. In 2005, the EMA introduced a well-balanced framework for its interaction with patients and consumers, which has been improved and updated over the past 15 years (see [revised framework](#)). This framework has further inspired many external parties, such as the European Patients' Academy on Therapeutic Innovation (EUPATI), the FDA, and the pharmaceutical industry, to establish or improve a structured, balanced, and meaningful approach to interacting with patients and the public.

Today, patients are fully active members on almost all of the EMA's working parties and decision-making committees. In 2020, the EMA reduced its activities due to the COVID-19 pandemic. Nevertheless, patients were involved in 102 scientific advice procedures, 42 scientific advisory groups, 228 committee consultations, and 203 document reviews (see the [EMA's website](#) for more PPI initiatives).

### European Patients' Academy on Therapeutic Innovation (EUPATI)

The [EUPATI](#) project was launched in 2012 and funded by the Innovative Medicines Initiative (IMI). The driving force of EUPATI is the idea that involving patients in medicines research and development has important benefits. To enable patient involvement, it is essential that the processes and methods are understood by patients and that patients learn where and how they can make a meaningful impact.

Today, EUPATI is a non-profit foundation that is structured as a multistakeholder public-private partnership. The EUPATI approach is now gaining ground within academic research as we understand patient involvement increases the impact of research and enhances its acceptance by society. A quarter of EUPATI's partners are academic research institutions. One of them is the [European infrastructure for translational medicine](#) (EATRIS), representing over 100 aca-

demical centres. Another collaboration was launched with [ERA PerMed](#), a funding scheme for research in personalised medicine. Through these collaborations, EUPATI seeks to enhance patient involvement and promote patients as active partners in the processes of academic research (see [EUPATI](#) article on [p. 22](#)).

Currently, the pool of EUPATI patient experts exceeds 200 individuals. They have been engaged in advisory roles, acted as trainers and speakers, supported patient organisations, reviewed trial protocols, and contributed to trial designs. Their involvement in academic research is increasing, as expressed by one EUPATI Fellow: "[I have been] involved in research activities and doing research and writing a scientific medical article, assessing proposals for medical research on the patient perspective."

## Patient Focused Medicines Development (PFMD)

Back in 2015, key stakeholders involved in the life cycle of medicines agreed that more effective patient involvement was needed to ensure that patients' needs and priorities are identified and met. Patient engagement was very productive in some areas but somehow isolated, inconsistent, and fragmentary within organisations, between organisations, in different stakeholder groups, and in different regions. This led to the creation of the [Patient Focused Medicines Development](#) (PFMD) initiative, a global network that includes over 35 partners from patient organisations, industry, hospitals, and the regulatory area with the aim of promoting a more patient-centred healthcare system that benefits patients and health stakeholders.

Progress toward a shared, replicable, scalable, and adoptable model for patient involvement requires a joint, precompetitive, open, and international approach by all stakeholders, including academic researchers. It is necessary for them to work in true partnership to map, analyse,

and consolidate good practices, to identify gaps, and to develop a comprehensive suite of methodologies, tools, and frameworks. This is the purpose of PFMD's [Patient Engagement Suite](#), which is a global hub of practical tools that can be used to plan, assess, and execute PPI initiatives.

In addition, the growing need from various stakeholders to consult the patient community for respective decision points has led to several multistakeholder initiatives aimed at harmonising the understanding of the patient experiences, and turning it into patient-centred, relevant data for various decision points across systems and stakeholder groups. One example of this is the PFMD's [Patient Engagement and Patient Experience Data](#) project, which helps better integrate stakeholder-specific needs and patient engagement in decision-making. Another example of such a project is the [Patient Centered Core Impact Set \(PC-CIS\) initiative](#), launched by the US National Health Council (a founding member of the PFMD).

## International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) published a [Reflection Paper](#) on patient-focused drug development in March 2021. The paper articulates key areas where the incorporation of the patient's perspective could improve the quality, relevance, safety, and

performance of drug development and inform regulatory decision-making. This paper is a first step towards new ICH guidelines aiming "to provide a globally harmonized approach to inclusion of the patient's perspective in a way that is methodologically sound and sustainable for both the regulated industry and regulatory authorities".

## Health technology assessment (HTA) bodies

Health technology assessment (HTA) bodies are also looking to promote a more systematic approach to patient engagement. The UK's [National Institute for Health and Care Excellence](#) (NICE) and its [National Institute for Health Research \(NIHR\) Centre for Engagement and Dissemination](#) as well as the [Canadian Agency for Drugs and Technologies in Health](#) (CADTH) and the international [Health Technology Assessment international \(HTAi\) Interest Group for Patient and Citizen Involvement in HTA](#) (PCIG) have delivered and are working on guidance or initiatives to better involve patients in decision-making and evidence generation. The pioneers of this approach were the pan-Canadian Oncology Drug Review agency (pCODR), which called for written input from oncology patient groups, and NICE, which established an early PPI team. Processes have been further enhanced by the HTAi

and adopted by many of the world's leading HTA bodies, including France's Haute Autorité de Santé (HAS) and the Scottish Medicines Consortium (SMC). A standard set of questions are now used by most HTA bodies to gain input on patient-relevant unmet needs and patients' experience of current healthcare practices. HTA bodies and regulatory agencies such as the FDA and the EMA are also progressing to more systematically incorporate the voice of the patient and patients' lived experience through the use of patient experience data (PED) in their review and approval processes for new drug submissions and value assessments (see related [EMA report](#)). These agencies are also adopting patient involvement practices within their early dialogues (scientific advice) with medicine developers.

## RECOMMENDATIONS FOR FUNDING INSTITUTIONS, APPLICANTS, AND PATIENTS TO INCREASE PPI IN ACADEMIC RESEARCH

The contributions of patients, caregivers, patient advocates, patient experts, and patient organisations to the design of clinical research and development have been well established through frameworks, tools, and educational resources by organisations and networks such as EUPATI, PFMD, and INVOLVE UK. However, applicants for research grants as well as funding bodies have experienced challenges putting systematic engagement with the patient community in collaborative research projects into practice. One exception to this is the [Patient-Centered Outcomes Research Institute \(PCORI\)](#) in the United States, which involves patients by design.

Patient representatives can play different roles when research projects are being designed, when collaborative groups apply for funding, and when research projects are being implemented. Within projects, patient engagement can be established in the funding framework, partnering concept, project design, grant application, application review, project implementation, and dissemination of project outcomes. Furthermore, funding institutions can engage patients to make sure that calls for proposals are focused on patients' unmet needs and that the quality of patient engagement is one of the criteria used when grant applications are evaluated.

The EU-funded IMI is a pioneer in this area, involving patient advocates in the definition of call topics as well as requiring patient involvement in some call texts. More recently, an [IMI pool of patient experts](#) was created with 157 patients and caregivers in order to further PPI. The IMI has also funded projects which were either led or co-governed by patient organisations (see [IMI's website](#) for a selection of projects). The European Commission has involved patient experts for years in independent review panels of their funding programme [Horizon 2020](#). However, the absence of a clear, cohesive PPI strategy for the EU has led to some dissatisfaction on many sides and needs to be developed.

To address the gaps in practical methods and models for how researchers and patients can engage in the different phases of collaborative research projects, the Switzerland-based [Rising Tide Foundation](#) and the think tank [Patvocates Network](#) have developed [recommendations and checklists](#) for funding institutions and applicants. These guidance documents include recommendations on how to involve the patient community before a collaborative research project starts, during the review of project applications, and during the implementation of a research project. They also describe how to bring researchers and the patient community together during the application phase, which practical engagement models and roles in the governance and implementation are feasible in collaborative projects, and how to measure the quality of patient engagement and compensation models.

In addition to an effective approach, patient engagement often requires technical knowledge like medical expertise, methodological expertise, and systems expertise. Therefore, it is essential to provide training for patient advocates so they can understand research and contribute to research projects effectively. Moreover, researchers need to receive training on how to involve patients in the most effective manner. Both [EUPATI](#) and the [Workgroup of European Cancer Patient Advocacy Networks \(WECAN\)](#) are examples of organisations that provide such training.

Some of the most important PPI initiatives in Europe and the United States are discussed above. Like every fundamental change, such developments take time, and established systems and processes need to adapt. Initiatives have proven most successful when they were carefully planned, included a long-term perspective, and legislative changes were made proactively. The progress in PPI that has been achieved so far can inform future efforts to promote and coordinate PPI in academic human research – with the goal of providing even greater benefits to patients and the public.

## Box 1: A selection of regulations, guidance, and initiatives on PPI in academic human research in Europe and North America

Location, Year	Regulation, guidance, or initiative	Related organisation	Purpose
USA, 1988	<a href="#">Investigational new drug, antibiotic, and biological drug product regulations</a>	US Food and Drug Administration (FDA)	Interim regulatory procedures to speed up the availability of new therapies to desperately ill patients; applicable to AIDS, some cancers, and other life-threatening diseases
USA, 1991	<a href="#">FDA Patient Representative Programme</a>	FDA	Mechanism for advocates to provide formal input to the FDA's decision-making process as medical products are regulated; first patient representative serves on the Antiviral Drugs Advisory Committee and receives voting rights in 1993
USA, 1993	Office of AIDS Coordination (est. 1988) renamed Office of AIDS and Special Health Issues	FDA	Build relationships with patient communities; broadened to include patients with cancer and other serious illnesses
European Union, 1996	Informal dialogue with (HIV) patients	European Medicines Agency (EMA)	Consider patients' perspectives regarding endpoints in pivotal trials to speed up approval
UK, 1999	<a href="#">Patient and Public Engagement Policy</a>	National Institute for Health and Care Excellence (NICE)	Involve patients, service users, caregivers, and the public – including voluntary, charitable, and community organisations – in its work
European Union, 2000	Patients become members of the EMA's Committee for Orphan Medicinal Products (COMP)	EMA	Include patients' perspectives on the committee
European Union, 2004	<a href="#">Regulation (EC) No. 726/2004 of the European Parliament and of the Council of the European Union</a>	European Commission (EC), EMA	Article 78(1) gives the EMA additional responsibility to develop contact with patients and consumers
European Union, 2005	Framework created for the EMA's interactions with patients and their organisations ( <a href="#">revised version</a> )	EC, EMA	Explain and consolidate the EMA's PPI methodology
European Union, 2006	<a href="#">Patients' and Consumers' Working Party (PCWP)</a>	EC, EMA	A discussion platform for patients and consumers to exchange information and ideas with the EMA
European Union, 2012	<a href="#">European Patients' Academy on Therapeutic Innovation (EUPATI)</a>	EU, Innovative Medicines Initiative (IMI)	Improve patient and public education and empowerment in order to improve medicines research
USA, 2012	<a href="#">Patient-Focused Drug Development (PFDD) initiative</a>	FDA	More systematically obtain the patient perspective on specific diseases and their currently available treatments
European Union, 2014	EMA's Public Engagement Department created	EC, EMA	Facilitate the EMA's engagement with the public
International, 2015	<a href="#">Patient Focused Medicines Development (PFMD) initiative</a>	Pharmaceutical industry, medical devices industry, patient organisations, patient networks, and individuals	Promote a more patient-oriented healthcare system
USA, 2015	<a href="#">Patient preference information (PPI) and guidance</a>	FDA, Center for Devices and Radiological Health (CDRH)	Incorporate the patient perspective in CDRH's regulatory decision-making
USA, 2020	<a href="#">Final patient-focused drug development (PFDD) guidance released</a>	FDA	Provide a systematic approach to collecting and submitting input and data from patients and caregivers for medical product development and regulatory decision-making
UK, 2020	<a href="#">Report of the Independent Medicines and Medical Devices Safety Review (Cumberlege Review)</a>	The Crown	Provide guiding principles for responding to and including patients' perspectives in improving the safety of medicines and medical devices and; recommend structural changes
European Union, 2020	<a href="#">EMA pandemic Task Force</a> with patient involvement	EMA	Provide a strategy for managing the COVID-19 crises and include patients in crisis management
International, 2020	<a href="#">New guidance, templates, and processes for patient summary information</a>	Health Technology Assessment international (HTAi)	Improve patient information; in use in Scotland and being piloted in England, Canada, Australia, and other countries
International, European Union, 2020	<a href="#">Tools and resources for HTA bodies</a>	HTAi via PARADIGM-IMI	Enable HTA bodies to quickly and effectively include patients early in the dialogue process
International, 2021	<a href="#">Reflection Paper on patient-focused drug development</a>	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	Promote PPI for improving drug development and regulatory decision-making; lay a foundation for new ICH PPI guidelines
UK, 2021	<a href="#">Innovative Licensing and Access Pathway (IALP)</a>	Medicines and Healthcare products Regulatory Agency (MHRA), NICE, Scottish Medicines Consortium (SMC)	Improve patient access to medicines by accelerating the time to market
UK, 2021	<a href="#">Proposed Patient and Public Involvement Strategy 2020–25</a>	MHRA	Develop and introduce clear PPI processes to ensure teams have a systematic means of engaging and involving patients and the public in their work
UK, 2021	<a href="#">MHRA pilot project on patient involvement in new applications</a>	MHRA	Place patient involvement at the heart of clinical trials and medicine development
Canada, 2021	<a href="#">Guidance for Providing Patient Input</a>	Canadian Agency for Drugs and Technologies in Health (CADTH)	Revised guidance to increase patient input in decision-making processes
Canada, 2021	<a href="#">CADTH Framework for Patient Engagement in HTA (revised)</a>	CADTH	Revised framework to promote PPI in HTA
UK, 2021	<a href="#">The NICE strategy 2021 to 2026</a>	NICE	Develop partnerships across the health and social care system, including with regulators and patient groups; introduce new PPI approaches to inform the evidence base for guidance development



## NEWS FROM



### GIVING PATIENTS AND THE PUBLIC A VOICE IN EVALUATING FUNDING APPLICATIONS FOR CLINICAL TRIALS

Authors: **Carolin von Schoultz**, **Deborah Studer**, and **Madlen Korneli**

Affiliations: Swiss National Science Foundation (SNSF)

Since 2016, the Swiss National Science Foundation (SNSF) has been funding investigator-initiated clinical trials (IICTs) on topics that lie outside of industry focus but are of significance to society. This year, patient and public representatives actively participated in the evaluation of applications submitted to this programme for the first time, a measure that has been overdue at the SNSF when compared to other European funders. The inclusion of the patient's perspective to "standard" clinical and statistical assessments added value to the evaluation and was an eye-opening experience for everyone involved.

#### HISTORY OF PATIENT AND PUBLIC INVOLVEMENT AT THE SNSF

*No decision about us without us* is a credo commonly used by representatives of patients and the public when it comes to their important role in clinical trials. Looking at the international landscape of patient and public involvement (PPI), we see that many funders are aligned with this vision. In the UK, PPI has been implemented in all healthcare research by organisations such as the [National Institute for Health Research \(NIHR\)](#). Specific [standards for public involvement](#) in UK research and [guidance for researchers](#) have already been established. In this guidance, the NIHR views public involvement in research as "an intrinsic part of citizenship, public accountability and transparency" and maintains it "helps ensure that research focuses on outcomes that are important to the public".

In order to foster a similar mindset in Switzerland and pave the way towards more patient-centred Swiss clinical trials, the SNSF added PPI as an evaluation criterion for IICT proposals in 2018. After two evaluation rounds, it became clear that assessing patient-centredness and patient relevance requires dedicated PPI representatives. As a result, the SNSF launched an open call for public participation at the end of 2020 and received over 50 applications. The SNSF was impressed by the tremendous response and the applicants' enthusiasm to bring the patient's view to the table.

The following four PPI representatives, all of whom have a background in patient advocacy and/or are active in the dialogue between society and research, were selected:

- Larisa Aragon Castro is the vice president of the Project Management Institute Switzerland and an executive board member of the European Patients' Academy on Therapeutic Innovation Switzerland (EUPATI CH).
- Chantal Britt is the communications officer at Swiss 3R Competence Centre and the founder and president of the Long Covid Switzerland association.
- David Haerry is the secretary general of the Swiss Academic Foundation for Education in Infectious Diseases (SAFE-ID) and the founder and president of Positive Council Switzerland, an advocacy organisation for people living with HIV.

- Olivier Menzel is the head of strategic partnerships at the Health 2030 Genome Center and the founder and president of the BLACKSWAN Foundation, which supports research on orphan diseases.

These PPI representatives were tasked with evaluating PPI aspects of the submitted IICT proposals, and they presented their views during the evaluation meeting. Equality among panel members is important at the SNSF, which is why the PPI representatives had a voting right during the evaluation meeting and were compensated for their efforts like all other panel members.

## TRAINING PPI REPRESENTATIVES

Together with an experienced PPI representative from the UK, the SNSF held a workshop to prepare the four representatives for their evaluation task. They had the opportunity to discuss and share their expectations of their role on the panel. As one of the highlights, the process of analysing and rating PPI strategies from past IICT calls led to a passionate discussion about how to distinguish between a researcher's mere *good intention* and *actively documented* patient involvement. An internal PPI checklist was a key outcome of the workshop. It lists possible ways of involving patients and the public over the lifetime of a clinical trial: from the initial study protocol design to its evaluation, trial course, dissemination,

and final impact assessment. The checklist guided PPI representatives through their proposal evaluations of the IICT call 2020, and it also served as the basis for the collaborative [PPI Guide for Researchers](#).

The representatives met four times before the evaluation meeting to discuss the applications assigned to them and develop a common approach. Each PPI representative was assigned a clinician from the Research Council as a personal contact to discuss any medical and clinical questions they might have. Through these personal meetings and support, the PPI representatives were well-prepared for the evaluation meeting.

## IICT EVALUATION MEETING

When all the preparations finally came together in the evaluation meeting, it was a joy to witness the confidence and ease with which the PPI representatives fulfilled their role on the panel. Matthias Peter, president of the Biology and Medicine division of the SNSF Research Council, chaired the evaluation meeting and states, “The views of the four representatives were a perfect complement to those of the clinicians and biostatisticians. I was impressed with their knowledge of current research around the world and their level of preparation.” PPI representative Larisa Aragon Castro remembers it as “a wonderful learning experience and an amazing journey. We felt very welcomed by the other panellists, and it was very satisfying to be able to make a difference and to have a vote. The panel members listened to us and understood in the end where we [as patient representatives] were coming from.” For the projects selected for funding in this round, PPI representative David Haerry notes, “In general, the scientifically excellent projects were also very good in terms of patient involvement.”

After the meeting, the PPI recommendations were sent to all applicants along with the clinical and statistical assessments.

## FUTURE OF PPI AT THE SNSF

This PPI pilot project at the SNSF was a great success. Irene Knuesel, head of the SNSF's Biology and Medicine division concludes, “This was the best possible outcome I could imagine and a great motivation to include PPI in the evaluation of all clinical research proposals at the SNSF.” The SNSF will continue collaborating with PPI representatives for the next IICT call and is evaluating the option to expand patient involvement to other SNSF funding schemes. In addition to its PPI pilot project, the SNSF produced the practical [PPI Factsheet](#) and the [PPI Guide for Researchers](#) in close collaboration with the Swiss Clinical Trial Organisation (SCTO) to help future applicants set up their PPI strategy.

Following are examples of feedback provided by the patient experts:

- A description of exactly how patients were involved in the development of the study design was missing. What was their input? How did it influence the study design?
- There was no information on the patient burden of the proposed study.
- The mandatory lay/public summary contained too much medical jargon and was thus hard for a non-expert to understand.
- The dissemination of the findings to patients and the public was not sufficiently described (e.g. the means of dissemination).

The PPI representatives' constructive feedback helped researchers whose projects could not be supported to revise their applications and, in particular, to refine their PPI strategy. Including PPI recommendations also emphasised to the applicants the importance of patient involvement in their trials.

Rather than adding to researchers' workload, developing a good PPI strategy should be seen as a valuable investment: it can improve participant enrolment, especially if it includes individuals with lived experience of the health condition under investigation (see [Crocker JC et al.](#)'s article in *BJM* from 28 Nov. 2018), and it can lead to more patient-relevant outcomes. “We hope that the SNSF's initiative speeds up the necessary and overdue cultural change in Switzerland to put PPI at the core of every clinical trial,” says Deborah Studer, head of the IICT programme. The following statement in a funded application summarises the “PPI spirit” the SNSF is striving for: “We can safely state that our patients and their families help us to identify outcomes that matter most to patients.”

## NEWS FROM

swissethics

Schweizerische Vereinigung der Forschungsethikkommissionen  
Association suisse des Commissions d'éthique de la recherche  
Associazione svizzera delle Commissioni etiche della ricerca  
Swiss Association of Research Ethics Committees

### SWISSETHICS: BUILDING TRUST AND INCLUDING PATIENTS' PERSPECTIVES IN THE HUMAN RESEARCH PROCESS

Author: **swissethics**

It has been widely proven that involving patients and laypeople throughout the entire human research process provides added value for human research in general, for patients in their everyday lives, and therefore for society as a whole. Public and patient involvement (PPI) is possible at the very early stages of research when defining objectives and planning a study, when a study is conducted, and when study results are published. PPI means that patients are treated as active research partners rather than just passive research subjects. This article discusses how swissethics promotes transparency in order to lay the foundation of trust needed for PPI and provides examples of PPI for the regulatory and ethical aspects of human research.

Patients and laypeople can contribute to clinical research in different ways: for example, they can actively participate in a research project or sign a general consent form, thus making their data and samples that are routinely collected in the hospital available to research. In recent

years, patient organisations have become increasingly professionalised, and today they offer their services and competencies not only to academia but also to industry, research institutions, and policymakers, among others.

#### PROMOTING TRANSPARENCY IN HUMAN RESEARCH

swissethics is convinced that involving patients and laypeople in clinical research and tapping into their motivation can generate the desired results only if there is complete trust between patients and laypeople and the researchers, institutions, and authorities involved in clinical research. Transparency and openness regarding the work swissethics does is one of the crucial pillars on which it builds trust. In order to promote this trans-

parency in human research for the general public, researchers, and institutions, swissethics launched the [RAPS](#) (Registry of All Projects in Switzerland) portal in May 2018. Additionally, since the start of the COVID-19 pandemic, it has regularly published lists of all studies that have been approved and all studies that have been submitted for approval conducted on SARS-CoV-2 and COVID-19 in Switzerland [on its website](#).

## INCLUDING PATIENT REPRESENTATIVES IN ETHICS COMMITTEES

Research ethics committees are composed of individuals from different professions, and they function as multidisciplinary panels to fulfil their duties to protect patients' rights and safety. Following the revision of article 53 (related to the composition of ethics committees) of the Human Research Act (HRA) that came into effect on 26 May 2021, at least one member of an ethics committee

must be someone who represents patients. Even before the recent revision of article 53, ethics committees were well aware of the benefit patient representatives and laypeople bring to the review of research projects and clinical trials. This is why some ethics committees have already been including patient representatives among their members since the HRA came into force in 2014.

## MAKING THE INFORMED CONSENT PROCESS MORE PATIENT-FRIENDLY WITH PPI

In a recent initiative of Professor Bernard Hirschel, President of the Ethics Committee Geneva, patient representatives and laypeople were actively involved in completely revising swissethics' templates for patient information and consent forms. In addition, swissethics started an important project in which the short forms of informed consent forms were completely redesigned. This project was based on linguistic work that was carried out by Professor Felix Steiner's team at the Zurich University of Applied Sciences (ZHAW) in Winterthur and that was

initially funded by the Federal Office of Public Health (FOPH). In due time, further interviews with patients, laypeople, and patient organisations will be conducted in order to gather their input on several other templates for informed consent forms. The fundamental objective for this total revision of the templates is to improve comprehensibility in general and to identify the most essential information that patients want to find in the informed consent forms.







## INVOLVING PATIENTS AND CONSUMERS IN SWISSMEDIC'S REGULATORY PROCESSES: FROM INFORMATION SHARING TO PARTICIPATION

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Affiliations: <sup>1</sup>Swissmedic, Deputy Head of Stakeholder Engagement and <sup>2</sup>Swissmedic, Media Spokesperson

The COVID-19 pandemic has highlighted the value of public engagement as a way of building confidence in innovative treatments, diagnostics, and vaccines for coronavirus-induced disease that have been brought to market readiness within a very short space of time. Developing public trust and engagement extends beyond providing transparent research results and evidence-based information to creating a framework for a dialogue that includes patients' perspectives. Whereas frameworks exist in the US, the UK, the Netherlands, and Germany, systematic patient involvement in Switzerland's healthcare system is still taking root. Even though Swiss policy-makers acknowledge the importance of stakeholder involvement in healthcare, tangible, overarching forms and systems of participation are only gradually being rolled out. Swissmedic, the Swiss Agency for Therapeutic Products, is also tackling the issue of how to integrate patients and the public into its regulatory processes. As it responds to this issue, Swissmedic aims to not only adopt current approaches but also actively create solutions that give patients a voice and incorporate their experiences and concerns into regulatory processes wherever possible.

A Google search for "patient and public involvement" or "patient engagement" results in over six million hits. This demonstrates that a widespread effort exists to involve patients and the public in the entire development and life cycle of therapeutic products. During the research and development stages, patient involvement can promote projects that are geared to patients' needs. Involving

patients in the approval process can help regulatory decision makers address any stakeholder needs that have remained unmet. Moreover, the market surveillance process benefits from user engagement: when product users identify warning signals early on, regulatory authorities can quickly initiate safety measures.

## SWISSMEDIC'S APPROACH TO PATIENT ENGAGEMENT

Regulatory authorities in different countries take different approaches to patient and public involvement. Whereas US patients or their representatives have seats on decision-making bodies at the Food and Drug Administration (FDA), other regulatory authorities involve patients in decision-making through patient interest groups or they consult patients during their decision-making processes. Compared to other countries, Switzerland is still in the early stages of finding tangible solutions that transform passive recipients and users of therapeutic products into active, well-informed participants.

As Switzerland's regulatory authority for therapeutic products, Swissmedic considers collaboration with all national and international stakeholders to be an essential part of fulfilling its legal mandate and reaching the defined objectives set out in its strategic goals. As the users and beneficiaries of safe therapeutic products, patients are considered important stakeholders in Swissmedic's national network. Swissmedic's cooperation with patients is rooted in the concepts of information exchange and active involvement in specific areas of its activities.

## PARTNERING WITH PATIENTS: ONGOING AND FUTURE PROJECTS

Early in 2014, Swissmedic launched a pilot partnership project that established a regular dialogue with patient and consumer organisations in order to more effectively take into account the needs and concerns of this stakeholder group and to obtain timely information on patients' experiences with therapeutic products. The newly formed Swissmedic Patient and Consumer Organisations Working Group met three to four times a year to discuss a range of key regulatory topics, such as the authorisation requirements and process for biosimilars, the legal basis for and relevant characteristics of patient information leaflets, and various aspects of the – at that time the new version (from 1 January 2014) – Human Research Act, including stakeholders' initial experience with its implementation.

In 2016, the project's pilot phase was extended for an additional two years based on the results of a survey of the working group and members' willingness to continue actively participating in the working group. The survey indicated that the project's goal of exchanging information had been achieved. However, the involvement of patient representatives in defined areas of Swissmedic's activities still fell short of expectations. After everyone involved in the working group unanimously agreed that it had made a valuable contribution to participation processes in the regulatory environment, Swissmedic decided

to continue this forum for exchanging information and experience beyond its four-year pilot phase. Between May 2014 and the end of 2020, the working group met a total of 25 times. It continues to meet regularly and currently includes 18 active member organisations.

In the upcoming years, Swissmedic will focus on the challenge of identifying in which regulatory processes patient and consumer participation is feasible and worth pursuing. To actively address this issue, Swissmedic launched a pilot project in July 2018 to incorporate patients' perspectives into the process of reviewing patient information leaflets. By the end of that year, the project's first candidate for a patient review had already been identified. In 2020, the pilot project was expanded to include additional indications and variations. The project is currently being fully implemented, giving all applicants an opportunity to involve patient organisations in the review of their patient information leaflets within Swissmedic's assessment process.

In addition, Swissmedic will relaunch a project in which patient representatives have the opportunity to review summaries of Swiss Public Assessment Reports (**SwissPARs**) that should be easily understood by laypeople (these [Public Summary SwissPARs](#) are available on Swissmedic's website).

## PARTNERING WITH LIKE-MINDED ORGANISATIONS AND INITIATIVES

Two of the aims stated in the updated [2021–2024 work plan](#) of Swissmedic's Patient and Consumer Organisations Working Group are to raise awareness of the group and increase its visibility. An additional goal is to partner with organisations and initiatives that are working on participation projects in Switzerland in areas aligned with the working group's activities. Swissmedic's partners include organisations such as the European Patients' Academy on Therapeutic Innovation Switzerland (EUPATI CH), the Patient Involvement in Development and Safe Uses of Medicines working group from the Council for International Organizations of Medical Sciences (CIOMS), and the Patient Advisory Board of the Swiss Group for Clinical Cancer Research (SAKK), an organisation that seeks to gather the experience and concerns of cancer

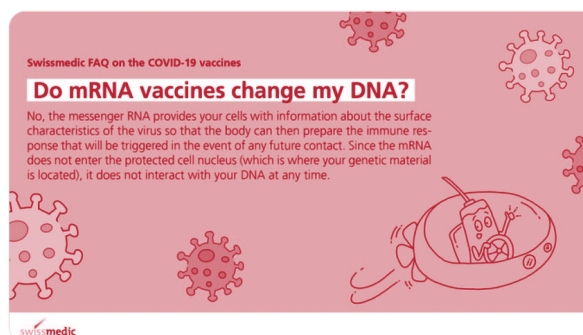
patients and their families and more effectively channel them into research. These partnerships help to avoid duplication and to use existing resources and capacities as efficiently as possible.

Like our partner authorities, Swissmedic supports patient engagement activities of international forums. For example, it contributed to the [Reflection Paper on Patient-Focused Drug Development](#) issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This reflection paper identifies key areas in which incorporating the patient's perspective could improve the quality, safety, and efficiency of medicinal product development and thus inform regulatory decision-making.

## INFORMING AND ENGAGING THE PUBLIC THROUGH SOCIAL MEDIA

In response to social media's growing influence on public opinion, Swissmedic established its social media presence in May 2020, which it continues to develop and expand. Swissmedic's social media platforms have become important sources of information for the public, especially during the COVID-19 pandemic. In the future, these media channels will include even more images, infographics, and videos and will be more interactive. This will allow Swissmedic's social media platforms to be more than just another broadcasting opportunity – they can become key tools for fostering a dialogue with the public and patients.

? #SwissmedicFAQ: Do #mRNA vaccines change my #DNA? 🧬👤



## A FRAMEWORK FOR THE FUTURE

Patient and public involvement in healthcare is increasingly being accepted as stakeholders' right to contribute to decision-making processes. For in the end, patients are the beneficiaries of healthcare and are therefore important stakeholders in the regulatory process. Plenty of work

awaits Swissmedic in the next few years as it continues to put into place its framework for partnering with patients and the public and incorporate their perspectives into its processes. Swissmedic is convinced that this work will lead to greater benefits for patients and the public.

## VIEWS AND OPINIONS



### POWER TO THE PATIENT: HOW EUPATI (CH) IS CHANGING THE FACE OF PATIENT EDUCATION

Authors: **Rosine Mucklow**<sup>1,2</sup> and **Caecilia Schmid**<sup>1,3</sup> with input from members of the EUPATI CH Executive Board

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The European Patients' Academy on Therapeutic Innovation (EUPATI) is an independent, non-profit foundation committed to changing the face of patient engagement through education. It provides training for patients and patient representatives on medicines research and development (R&D). EUPATI Switzerland (EUPATI CH) is the official Swiss EUPATI National Platform and acts as a central point for inquiries and cooperation for patient empowerment and involvement in medicines R&D in Switzerland. After successfully launching the increasingly popular annual Swiss Patient Forum (SPF) in 2017, EUPATI CH is currently developing a Swiss training module for Swiss patients and patient representatives who wish to be involved in patient engagement activities and who are interested in learning about the Swiss legal and ethical framework for clinical R&D in one of Switzerland's national languages.

Involving patients in research can provide a significant benefit to the medicines development process. Patients can contribute to developing better treatments for themselves and others by sharing their priorities and

perspectives. Experience has shown that greater patient involvement in R&D increases the efficacy and safety of new treatments and increases public support for medical research.

### EUPATI: EMPOWERING PATIENTS THROUGH EDUCATION

[EUPATI](#) was launched as a flagship project of the Innovative Medicines Initiative (IMI) in early 2012. The project aims to trigger a major rethink in the way patients and the public understand medicines development and their own involvement in the medicines development process. Equipped with a deeper understanding of this process, patient experts are empowered to work effectively with relevant authorities, healthcare professionals, and industry partners to influence medicines development for the benefit of patients and the public.<sup>1</sup> The main goal of the EUPATI project is to develop and disseminate accessible, well-structured, comprehensive, scientifically reliable, and user-friendly educational material to patients.

The EUPATI project provides [educational resources](#) in key areas of medicines research and development that have been translated into several languages under Creative Commons licenses.

The educational resources are aimed at two main audiences:

- The EUPATI [Toolbox](#) is intended for education-level patients with little or no prior knowledge of the topic.
- The EUPATI [Open Classroom](#) (a newly designed version of its [Patient Expert Training Programme](#)) is intended for expert-level patients who are already experienced, knowledgeable advocates.

Following the huge impact of the pioneering and well-recognised EUPATI Patient Expert Training Programme, which has been conducted in four cohorts since its start in 2015, EUPATI recently launched a new format called Open Classroom. This new format enables participants to take courses online or on-demand at their own pace and in their preferred sequence.

### EUPATI CH: PROMOTING PATIENT INVOLVEMENT IN SWITZERLAND

In parallel with its international activities, EUPATI has established [National Platforms](#) in more than twenty countries, including Switzerland, with the aim of bringing patient, academic, and industry partners together to foster patient education and involvement in medicines R&D at a national level.

The Swiss National Platform [EUPATI CH](#) was formed as an association in November 2016. As stated in its statutes, the association is fully committed to acting as a central point for inquiries and as a cooperation platform for patient empowerment and involvement in medicines R&D in Switzerland. The EUPATI CH association consists

of a steadily growing number of members who form the General Assembly, an Executive Committee that oversees strategic operations, and an Advisory Board that is currently in the planning phase.

Since its inception, EUPATI CH has promoted awareness of EUPATI and its educational resources by actively participating in various public events and conferences throughout Switzerland. In 2017, EUPATI CH successfully launched the [Swiss Patient Forum](#), an increasingly popular annual event whose programme is co-developed by EUPATI CH members and external experts; the event is sponsored by industry.

<sup>1</sup> See the EUPATI project's [2017 Executive Summary](#), which can be downloaded from its website.



## SWISS TRAINING MODULE: TRAINING PATIENTS TO BECOME CLINICAL RESEARCH PARTNERS

More recently, EUPATI CH decided to create a Swiss training module, its own national training programme to empower Swiss patients and patient representatives to contribute as partners in the design, planning, and conduct of clinical research through patient engagement. In contrast to the EUPATI Open Classroom, the Swiss training module can be done by patients and patient representatives with little or no prior knowledge of the topic. It will offer an introduction to clinical research and patient engagement for Swiss patients in a national language (German) and will be adapted to the Swiss legal framework and regulatory environment for research involving human beings.

Thanks to its flexible structure (similar to that of the Open Classroom), the Swiss training module will accommodate the special needs and often challenging schedules of prospective participants. To do this, it will offer a blended learning format and modular structure, thereby allowing for greater flexibility as to when and where content can be completed. The course will consist of three basic mandatory modules that will introduce the topic of research, including ethical and legal aspects,

and will consider why the latter aspects are important for improving healthcare. In addition, four voluntary advanced modules will be offered that focus on specific aspects of clinical trials and how patients can become involved in them. Generally, each module will last 12–15 hours and will be available online; each module will also include virtual Q&A sessions and face-to-face training sessions. At the end of each module, participants can either take a short test or complete written assignments in order to obtain a certificate of completion.

The Swiss training module is currently being developed in close collaboration with the Department of Clinical Research (DKF) of the University Hospital Basel. EUPATI CH plans to launch the programme in early 2022; the exact date will be confirmed once sufficient funding has been secured. The Swiss training module will allow EUPATI CH to train patients for the ever-increasing number of opportunities for patient involvement in Switzerland. Looking ahead, EUPATI CH continually seeks interesting initiatives related to patient education and remains grateful for input from the public.

## VIEWS AND OPINIONS

# ProRaris



Alliance Maladies Rares – Suisse  
Allianz Seltener Krankheiten – Schweiz  
Alleanza Malattie Rare – Svizzera



### PROMOTING INCLUSIVE, PATIENT-ORIENTED RESEARCH: A RARE DISEASE PATIENT PERSPECTIVE

Authors: **Therese Stutz Steiger**<sup>1,2</sup> and **Olivier Menzel**<sup>1,3</sup>

Affiliations: <sup>1</sup>ProRaris Swiss Alliance; <sup>2</sup>Swiss Osteogenesis Imperfecta Association (SVOI), former president; and

<sup>3</sup>BLACKSWAN Foundation for research on orphan diseases, chairman and founder

Patients and members of the public contribute valuable information and perspectives to research projects because they have experienced a disease themselves or are close to someone affected by an illness. Patients with rare diseases are incredibly motivated to participate in research projects. Any advancement of scientific or medical knowledge or favourable political decisions can increase the possibility of a cure – or at least a treatment – that can stop or slow the progression of their disease and improve their quality of life. Patients' lived experience may help researchers fill gaps in understanding conditions that they know mainly from theory. In this article, the authors address the need for more focus on patient-oriented clinical and public health research, the importance of bringing patients' perspectives into research, issues around patient involvement, and areas for future research on the topic.

Rare diseases severely impact people's everyday lives and the lives of those around them: they often face overwhelming time, health, and social costs. For support, patients and their caregivers are often involved in patient organisations such as [ProRaris](#), an umbrella organisation that advocates

for patient groups and patients in Switzerland living with a rare disease. Patients and patient organisations can help provide researchers with an insider's perspective on their health conditions, thus improving research related to a cure or treatment (FOPH 2014).

## FOCUS ON PUBLIC HEALTH RESEARCH

According to the Organisation for Economic Co-operation and Development's (OECD's) 2001 definition, biomedical research encompasses the full spectrum of health- and disease-related research, from basic research to public health research through to clinical research (OECD n.d.). However, the understanding of biomedical research is now commonly restricted to discovery research and thus does not cover the full range of health-related research. Public health research (Egger et al. 2021), by nature observational, focuses on the evaluation of population health and well-being and patient experiences (Moreau et al. 2021). This research typically happens outside of the controlled clinical setting of experimental or interventional research and aims to improve the physical and mental aspects of the

human condition through longitudinal, interdisciplinary, multi-methodology research. The well-funded biomedical approach to research is oriented towards developing technological solutions that can be commercialised. An excellent recent example is the development of SARS-CoV-2 vaccines. Public health research is often neglected, yet an increased focus on such research could address many patient-oriented topics, including:

- patients' criteria for quality of care
- how patients perceive interdisciplinary and inter-professional collaboration
- patient self-management
- patient empowerment
- life-course and transition challenges.

## PATIENT INVOLVEMENT IN RESEARCH: "NOTHING ABOUT ME WITHOUT ME!"<sup>1</sup>

Patient and public involvement (PPI) in research (biomedical or public health) means that a research project is carried out "with/by" patients or the public.<sup>2</sup> Patients' opinions must have a more significant influence on the decisions that affect them. Care that is respectful of and responsive to their preferences cannot be provided without patients' participation in both their own healthcare decisions and the research that informs such decisions.

It is important to emphasise that patients do not all share the same experiences and skills, and they are not all willing to be involved to the same degree in research. Moreover, different studies may have different needs for patient involvement. What is certain is that all patients can contribute to some degree and make a difference at every stage of research (see **Box 1** on the next page).

<sup>1</sup> From Valerie Billingham during session 356 of the Salzburg Global Seminar in 1998 entitled Through the Patient's Eyes.

<sup>2</sup> Adapted from the National Institute for Health Research (NIHR) INVOLVE's supporting statement (<https://www.invo.org.uk>).

**Box 1: Degrees of patient expertise and involvement**

Level of expertise	Description
Lay patients	<ul style="list-style-type: none"> <li>• Have a passive role in their healthcare and no experience with PPI</li> <li>• May be looking to become a member of a patient organisation</li> <li>• Have not had medical training or expertise in any profession linked to medicine or the life sciences</li> </ul>
Patient actors/partners	<ul style="list-style-type: none"> <li>• Participate in their healthcare (on an individual level) and act as advocates more globally (on a collective level)</li> <li>• Are likely a member of a patient organisation</li> <li>• Do not necessarily have experience with PPI or in the medical field</li> </ul>
Patient experts	<ul style="list-style-type: none"> <li>• Have experience with PPI or play an active role in a patient organisation (Stutz Steiger 2016)</li> <li>• May be members of a patient organisation's committee/board and thus have relevant skills and experience</li> <li>• Can take on multiple roles with or without other patients, can partner with health professionals, and can act as a trainer or research partner</li> <li>• Frequently have medical training or are in a profession linked to medicine or the life sciences</li> </ul>

**PPI CONSIDERATIONS: COMPENSATION AND SELF-MANAGEMENT**

PPI depends on patients sharing their expertise. Rare disease patient expertise is in increasingly high demand for various reasons, including a lack of understanding of many rare diseases, lobbying with drug agencies, patient recruitment, and fundraising (Halsbeck et al. 2016). The PPI aspects of a research project and patient experts' contributions require a considerable time investment. To attract enough PPI contributors, they must be adequately compensated financially, beyond any non-material benefits they may experience by contributing. This argument favours having more PPI contributors considered active members of a project team (Pomey et al. 2021) and on the project's payroll.

Self-management refers to how people who are affected by a chronic condition manage their health and themselves (FOPH 2018). Self-management requires striking a balance between enabling patients to manage their health, not putting them under too much pressure to do so, and not setting unrealistic self-management goals. For patients with low self-management, actively participating in a research project can be a source of additional stress. Patients with high levels of self-management are excellent candidates for PPI in research projects, primarily due to their ability to critically reflect on their health situation. Including their perspectives on self-management and other patient-relevant topics can significantly improve participative research study designs.

**PPI IN FUTURE RESEARCH**

Comprehensive and practical PPI can be challenging to achieve (NHS Health Research Authority n.d.). The first step is involving patients. Involving the wider public raises additional methodological questions but might be particularly important for preventive (e.g. vaccination) and screening interventions targeting non-diseased persons. Biomedical and public health researchers should remember that the main objectives of their research are to prevent disease, promote its early detection where

appropriate, cure illness where possible, or improve treatment and thus improve patients' quality of life. PPI can be a powerful tool in helping retain the focus on these objectives (see PPI action points in **Box 2** on the next page). In light of all these considerations, the research agenda for the next ten years must include PPI. In Switzerland, a dedicated national research program addressing ways to organise PPI and, more generally, citizen science is overdue.

## Box 2: PPI action points

- Introduce incentives for patients and public involvement in research
- Emphasise that knowledge of disease pathogenesis is essential but patients are not just research subjects
- Encourage patients to participate in health literacy and become active members of research teams
- Increase interdisciplinarity with patient inclusion to improve patient recruitment and participation
- Expand Switzerland's national concept on rare diseases to include the interaction between action and research (see the Federal Office of Public Health's current [National Rare Disease Policy](#) (in German))

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## VIEWS AND OPINIONS



Schweizerische Akademie der Medizinischen Wissenschaften  
Académie Suisse des Sciences Médicales  
Accademia Svizzera delle Scienze Mediche  
Swiss Academy of Medical Sciences



### TOWARDS MORE INTEGRATIVE, PATIENT-CENTRED CLINICAL RESEARCH

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What does clinical research in Switzerland need in order to increase its benefit to patients and society? What changes are necessary? This year, the Swiss Academy of Medical Sciences (SAMS) published its White Paper: Clinical Research, which formulates seven goals that bring together clinical research stakeholders around a shared vision. This vision – to strengthen the impact of clinical research – is based on a solid partnership with patients and the public.

Patient-oriented clinical research has improved in the past twenty years thanks to public investment in several initiatives (e.g. the creation of clinical trial units (CTUs), the establishment of the Swiss Clinical Trial Organisation (SCTO), local clinical MD-PhD programmes, and the Swiss Group for Clinical Cancer Research (SAKK) regional networks project), infrastructures (e.g. data warehouses, biobanks, analytic platforms, the Swiss Personalized Health Network (SPHN), and the Swiss Biobanking platform (SBP)), and support instruments (e.g. Swiss National Science Foundation (SNSF) grants for longitudinal studies, funding for investigator-initiated clinical trials (SNSF's IICT programme), and the SAMS and Bangerter Foundation's joint programme Young Talents in Clinical Research (YTCCR)).

However, these efforts have also led to a fragmentation of activities, and deficits remain – including limited integration and harmonisation of processes within and between institutions, insufficient involvement of patients, a lack of incentives to choose a career in clinical research, weak multidisciplinary and interdisciplinary research, and uncertain sustainable funding for research infrastructures and early career researchers. Moreover, despite the high quality of medical care in Switzerland, Swiss clinical research still lags behind basic and experimental research and behind clinical research in leading countries when compared internationally.

Written on behalf of the State Secretariat for Education, Research and Innovation (SERI), the [White Paper: Clinical Research](#) analyses the major driving forces that are transforming clinical research and identifies current weaknesses in clinical research in Switzerland. Based on the notion that good care comes with – and from – good science, the white paper calls for a transformation of the clinical research culture in hospitals and related research institutions so as to make it more integrative at all levels.

The white paper also provides a roadmap that outlines the following seven goals and constitutes an action plan for change to make Switzerland an international leader in patient-centred clinical research:

1. Create a national platform to coordinate publicly funded stakeholders in clinical research.
2. Establish strong partnerships with society, the public, and patients.
3. Promote a healthcare system that systematically integrates clinical research: good care comes with – and from – good science.
4. Invest in the development of innovative and dynamic clinical research approaches, designs, and technologies enabled by digital tools.
5. Strengthen translational, multidisciplinary, and integrated clinical research teams.
6. Create an environment that is attractive to clinical and health researchers and support them at all career levels.
7. Increase the efficiency of clinical research and accelerate its delivery by reducing the complexity of regulatory and data-related processes.

In order to increase the benefit of research to society as a whole, patients and the public should be involved in strategic discussions and funding decisions related to clinical research. Along with innovation and novelty, evaluation criteria for research grants should include addressing unmet medical needs and achieving patient-relevant outcomes. In addition, public campaigns should emphasise both the value of partnerships between scientists, patients, and the public and the importance of clinical research for high-quality healthcare. Moreover, initiatives to create a national framework for patient and public involvement and empowerment need to be promoted and coordinated.

A PDF of the White Paper: Clinical Research can be downloaded or a printed copy can be ordered free of charge on the [SAMS website](#). The website also contains information on creating a national coordination platform to strengthen the interaction between all public stakeholders of clinical research and integrating the perspective of public health.



## CASE STUDY

### GENEVA UNIVERSITY HOSPITALS



## PATIENT ENGAGEMENT IN CLINICAL RESEARCH: GENEVA UNIVERSITY HOSPITALS' MODEL

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Affiliations: <sup>1</sup>Patient partner and <sup>2</sup>Geneva University Hospitals (HUG) Clinical Research Partnership Team (PARTNER REC)

While the concept of patients as partners in clinical research is becoming increasingly prevalent, there is still room for improvement. The development and validation of partnership models to engage patients in the design and governance of clinical research programmes are still in the early stages, and approaches that can ensure substantial and effective patient contributions to research are needed. In this article, we describe the patient partnership model being developed at Geneva University Hospitals (HUG) to engage patients and their caregivers in the design of clinical research studies and to encourage research groups in their efforts to involve patients within their teams.

Patient engagement in clinical trials and other health research continues to gain momentum. Once regarded as passive “subjects” who had research performed on them, patients are now contributing across the spectrum of clinical development, including in the design and planning of research protocols, the selection of outcomes and end-

points, the development of recruitment strategies, and the dissemination of research results (see [Uhlenbrauck et al.](#)'s article in *Applied Clinical Trials* from 8 February 2018). Yet as recent research confirms, partnering with patients in clinical research needs to be improved (see [Calaprice-Whitty et al.](#)'s article in *Applied Clinical Trials* from 31 May 2017).

Research activities are an integral part of the mission of Geneva University Hospitals (HUG) and are carried out in close collaboration with the University of Geneva's Faculty of Medicine and Geneva's High School Health (HEDs). For this reason, a model of patient engagement in clinical research, which is overseen by the Clinical Research Partnership Team (PARTNER REC), was developed in 2019 and is supported by the HUG General Directorate. The ultimate goal of the model is to enhance the speed and quality of clinical research at HUG.

PARTNER REC brings together patients, researchers, caregivers, doctors, members of the regional research ethics committee, and partnership professionals. The working group was originally designed to provide patients and research professionals with a toolbox, or methodological support, that informs researchers and patients on why, who, when, and how to involve patient partners in a research project protocol. This toolbox presents the following information for each step of a research project, from the identification of the research question to the dissemination strategy:

- examples of possible patient/public involvement for each stage (see **Table 1**)
- the value of such collaboration to the researcher
- the interest of the collaboration for the patient/member of the public.

In addition to developing the toolbox, since 2020 PARTNER REC has invited clinical researchers on a regular basis (every month) to present and discuss the possibilities of partnership with patients for the different stages of their projects. These sessions are led by patient partners, medical practitioners, and nursing professionals who are experts in research and partnership.

The partnership took a further step forward in 2021 by incorporating the contents of the toolbox into an [information website](#) for professionals and the general public (in French; will soon be available in English). Depending on their interests, level of knowledge, availability, and wishes, patients and the public can join a research team and participate in the following activities:

- developing a relevant research question
- preparing the study plan and presenting it to the general public
- recruiting participants
- collecting data, for example by interviewing patients
- interpreting research results.

Two key concepts for PARTNER REC are transparency and collaboration. Patients are considered more than just subjects of observation – they become full partners by contributing to one or more stages of the scientific knowledge production chain.

**Table 1: Examples of possible patient and public involvement during clinical research stages**

Clinical research stage	How patients and the public can be involved
<b>Choice of the research topic</b>	<ul style="list-style-type: none"> <li>• Participate in surveys and focus groups on the relevance of the study topic</li> <li>• Propose a research theme or topic</li> </ul>
<b>Elaboration of the protocol</b>	<ul style="list-style-type: none"> <li>• Proofread, revise, and/or co-write parts of the study protocol</li> <li>• Discuss, advise on, and/or test the relevance of patient-centred outcomes</li> <li>• Proofread, edit, and/or co-write patient information</li> </ul>
<b>Conduct of the study</b>	<ul style="list-style-type: none"> <li>• Contact patient organisations to inform them about the study and facilitate the recruitment of interested patients</li> <li>• Liaise between the patients participating in the study and the research team in order to obtain feedback on their experiences and impressions</li> </ul>
<b>Interpretation of the results</b>	<ul style="list-style-type: none"> <li>• Discuss the appropriateness of intermediate or final results</li> <li>• Modify patient information, if necessary</li> <li>• Discuss the relevance of the results</li> </ul>
<b>Writing and publishing</b>	<ul style="list-style-type: none"> <li>• Participate in writing and proofreading the research article</li> <li>• Disseminate study results via patient organisation networks</li> <li>• Set up patient forums to inform others about the study results</li> <li>• Review documents that are intended for the public and/or published on HUG websites</li> <li>• Become involved in public events related to the research study</li> </ul>
<b>Implementation and change of practice</b>	<ul style="list-style-type: none"> <li>• Help develop recommendations for better hospital management</li> <li>• Advise on the practical aspects of implementing recommendations</li> </ul>

## CASE STUDY

### UNIVERSITY HOSPITAL BASEL



## THE VALUABLE INSIGHTS OF PATIENTS: TWO CASE STUDIES

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Because of their lived experience, patients provide unique insights and perspectives on clinical research studies. This article presents two case studies from the University Hospital Basel that illustrate how researchers and patients can collaborate to shape research priorities and study design as well as assess study feasibility.

### CASE STUDY 1: USING PATIENT INVOLVEMENT TO INFORM RCT STUDY DESIGN

Following weight loss surgery, 25–30% of patients experience hypoglycaemia after meals, which is a serious complication that can severely impact their quality of life. Since symptoms frequently arise well after surgery, they are often not identified at control visits. The underlying mechanisms of this hypoglycaemia are not well understood, and there is no approved medical treatment for its symptoms.

In a pilot study with a small group of patients conducted by Dr Matthias Hepprich, senior physician and researcher at the University Hospital Basel and the Cantonal Hospital Olten, two different drugs showed promising results in terms of reducing postprandial insulin release and preventing hypoglycaemia (Hepprich et al. 2020a). To

design a larger randomised controlled trial (RCT), the study team wanted to measure patient-relevant outcomes and try to obtain new information about the underlying mechanism of the hypoglycaemic episodes (Hepprich et al. 2020b). Systematic searches of literature, relevant databases, patient resources, and groups on the internet did not yield helpful information. The team then approached several patients in the clinic and from the pilot study mentioned above to identify relevant topics using a preliminary questionnaire to guide discussions. Identified topics were ranked by two of the most severely affected patients in the clinic. Because a broad range of topics were identified as important, the researchers suggested measuring the quality of life.





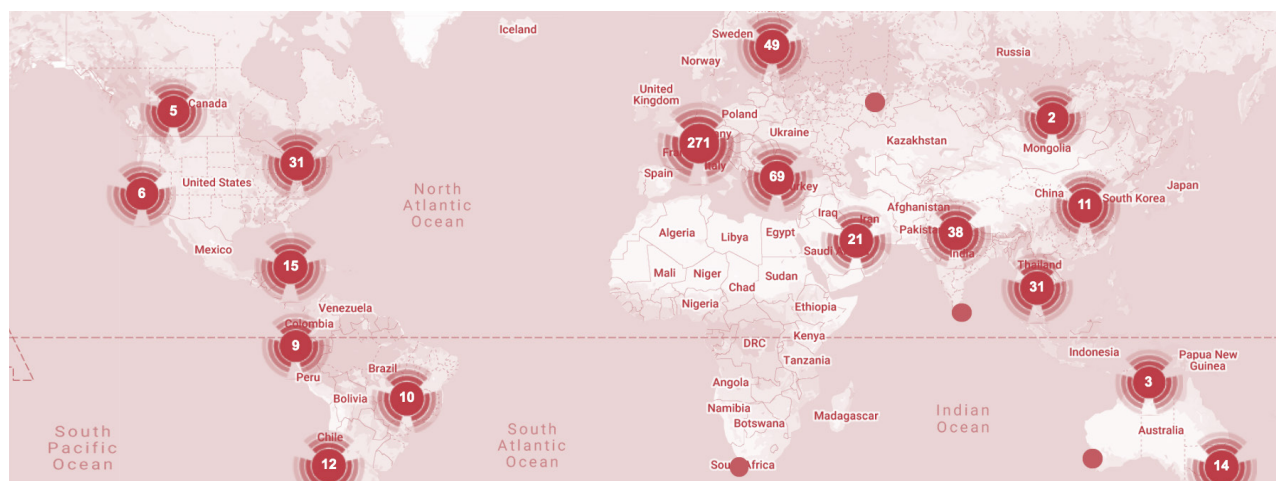
Study team

Based on the acquired information, an anonymous questionnaire containing questions on the primary endpoint and trial length along with information about patients' medical history was developed and distributed to patients with the help of healthcare providers. Filling out the questionnaire was voluntary, and the answers from it led researchers to include quality of life as a primary outcome along with the number of hypoglycaemic episodes in the trial design. In addition, the questionnaire helped researchers determine the length of the study's interventional phase.

Both Hepprich and one of the patient representatives involved in the generation of the questionnaire viewed the experience as positive. For Hepprich, the entire process – from searching literature to obtaining the results of the questionnaire – was very valuable, interesting, and fun. He found actively engaging in discussions with patients and learning more about their priorities to be tremendously rewarding (rather than solely generating his own theories or discussing ideas exclusively with research colleagues). As tips for other researchers, Hepprich recommends thoroughly researching what information from patient involvement is already available and if patient-relevant outcomes have already been established.

The patient representative interviewed reported that she would be happy to participate in the evaluation of clinical trial protocols again in the future; she finds that only through feedback can one ultimately achieve improvement. Moreover, she found that the discussions with Hepprich and his colleagues about the current study were not very time-consuming. She would be willing to participate in clinical studies as a participant in the future and offered some general tips for researchers planning a study. One tip is that participants are more motivated when, for example, their treating physician or care personnel approach them personally for participation than when they receive a standard letter or form in the mail. And when reading the participant information sheet, participants can tell if researchers have taken the time to write the information specifically for their trial or if it is a standard text. In addition, good coordination of the visit plan, for example coordination with routine treatment visits at the hospital, makes a significant difference.

## CASE STUDY 2: PATIENT ADVOCATES AND SURGEONS JOIN FORCES TO IMPROVE BREAST CANCER SURGERY



Locations of OPBC members

Oncoplastic breast surgery combines traditional breast cancer surgery techniques and plastic surgery techniques with the aim of removing cancer while considering aesthetic outcomes and quality of life for the patient (Columbia Surgery n.d.). Professor Walter Paul Weber, Chief Physician of Breast Surgery and Head of the Department Brust, Bauch und Becken (department of breast, abdomen, and pelvis) at the University Hospital Basel, initiated the Oncoplastic Breast Consortium (OPBC) after having positive experiences with patient involvement. The OPBC brings together more than 500 breast cancer surgeons and 42 patient advocates from around the world with the mission to improve oncoplastic breast surgery through collaboration, research, and education. Patient advocates are involved in shaping research by:

1. evaluating clinical trial protocols in terms of feasibility, acceptability, and relevance from the patient's perspective
2. helping define research priorities and develop concrete research questions for OPBC researchers to address.

Jane Shaw, OPBC's Global Patient Advocacy Lead, coordinates the patient advocacy group and meets regularly with Weber.<sup>1</sup>

A recent OPBC initiative brought together patient advocates and surgeons to define the 15 most important knowledge gaps in oncoplastic breast surgery and select 7 research priorities based on these gaps (Weber et al. 2020). Currently, the OPBC is starting its first patient-driven research project centred on aesthetic flat closure. This specific surgical option consists of a mastectomy without reconstruction, executed to rebuild the shape of the chest wall so it appears flat. First, a questionnaire for OPBC surgeons will gather information about their awareness, practices, and attitudes related to this option. Second, patients' experiences with the aesthetic flat closure option will be evaluated.

For researchers interested in patient involvement, Weber recommends getting in touch with patients early – as soon as an abstract of a planned study has been developed – to discuss the endpoints and feasibility of the study. By doing this, researchers can ensure that they investigate aspects relevant to patients, and they have the chance to improve recruitment and retention rates in their studies. Working with patient advocates can be demanding because both sides have different perspectives and experiences. However, patient involvement has an obvious added value and helps ensure that researchers do not miss the mark in terms of addressing patients' needs.

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<sup>1</sup> More information about Jane Shaw and her journey to patient advocacy can be found in an online [article](#) in the *Henley Standard* newspaper.

## INNOVATION CORNER

swiss  
clinical  
trial  
organisation



### INVOLVING PATIENTS IN ACADEMIC CLINICAL RESEARCH: IT'S TIME TO WALK THE TALK

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Affiliations: Swiss Clinical Trial Organisation (SCTO) and European Patients' Academy on Therapeutic Innovation Switzerland (EUPATI CH), executive board member

Involving patients in academic clinical research ensures that research questions and clinical research outcomes are addressed and implemented in a manner relevant to patients. As one of our key strategic goals in the new 2021–2024 performance period, the Swiss Clinical Trial Organisation (SCTO) and its Clinical Trial Unit (CTU) Network are placing greater emphasis on the implementation of patient and public involvement (PPI) in academic clinical research. In pursuit of this strategic goal, the SCTO sent out a survey to relevant stakeholders in order to identify and characterise all PPI initiatives and projects in Switzerland and thereby establish the status quo. As a next step, the SCTO envisions establishing a central coordination and contact point that is pathology-independent and spans organisations. We aim for a sustainable, inclusive PPI approach in academic clinical research that is established in close collaboration with our partners and stakeholders.

The [Swiss Clinical Trial Organisation](#) (SCTO) and its [Clinical Trial Unit](#) (CTU) Network are strongly committed to clinical research being patient relevant. This patient relevance is anchored in the SCTO's [vision and mission statements](#), and many of our past activities reflect this

commitment. The SCTO is one of the founding members of Switzerland's European Patients' Academy on Therapeutic Innovation ([EUPATI CH](#)) and has run the association's secretariat on an in-kind basis since its inception.

## PATIENT AND PUBLIC INVOLVEMENT AS A STRATEGIC GOAL FOR THE NEXT FOUR YEARS

In the SCTO's new 2021–2024 performance period, even greater emphasis will be placed on implementing patient and public involvement (PPI) in academic clinical research as one of our key strategic goals. There is no denying the fact that patients can offer a unique perspective on clinical research.<sup>1,2</sup> Through their experience with a disease or condition, patients know best which aspects are most relevant to them. By sharing this specific knowledge, they contribute to the quality, feasibility, relevance, and

credibility of clinical research. Along with other important benefits, this can improve a clinical trial's recruitment rate and potentially patient retention and thus enhance the success of a trial. From an ethical point of view, one can argue that patients should have an influence on research that affects them, in line with the motto “nothing about us without us” (see the SCTO's [PPI Factsheet](#) and [PPI Guide for Researchers](#) for more PPI information).

## CURRENT PPI SITUATION IN SWITZERLAND

In reality, the practical application of PPI in academic clinical research is lagging behind in Switzerland when compared to other European countries such as the UK or the Netherlands.

Some initiatives exist that have been put in place by single organisations, but they more or less stand alone and are not connected. Yet they face similar problems and need to address comparable challenges. And above all, they rely on the same “resource”: patient and public representatives who are willing to contribute and actively engage in PPI. Because the PPI approach is relatively new, trained and empowered patients who are able to make a more informed contribution are still a scarce resource in Switzerland. In addition, transparent compensation models for patients' contributions are often missing or insufficiently established due to a lack of funding. This does not support sustainable PPI implementation in the long run.

The SCTO is therefore advocating for a more holistic, adequately funded, and coordinated PPI approach that

includes different organisations and stakeholders and pursues the following objectives:

- build and leverage available resources
- use synergies where possible
- raise awareness of the concept of PPI
- implement the principles of PPI and realise its benefits in the most efficient and sustainable manner possible
- raise the visibility of clinical research and its significance for public health
- establish the trust and mutual confidence between patients/the public and the research community needed to lead to a true partner relationship.

In our endeavours to foster the implementation of PPI in academic clinical research, the SCTO is taking a stepwise approach and including all relevant and interested stakeholders as we go along.

<sup>1</sup> Grading F et al. (2015) Values associated with public involvement in health and social care research: A narrative review. *Health Expectations* 18(5):661–675. doi:<https://doi.org/10.1111/hex.12158>

<sup>2</sup> Crocker JC (2018) Impact of patient and public involvement on enrolment and retention in clinical trials: Systematic review and meta-analysis. *BMJ* 363:k4738. doi:<https://doi.org/10.1136/bmj.k4738>



FIRST STEP: A MAPPING EXERCISE

As the first step, a multistakeholder working group was established in December 2020. This group developed and sent out a [survey](#) to identify and characterise all PPI initiatives and projects in Switzerland with the aim of

defining the status quo. The initial results of the survey are currently being analysed and will be summarised and published on the SCTO’s website at the beginning of next year.

SECOND STEP: ESTABLISH A SWISS PPI HUB

As a second step, the SCTO envisions establishing a central coordination and contact point that is pathology-independent and spans organisations (working title: Swiss PPI Hub). The conceptional framework for this Swiss PPI Hub will be built upon the results of the mapping exercise performed in the first step with the objective of bringing all relevant and interested stakeholders on board. Preliminary reflections on how the potential Swiss PPI Hub could be set up are depicted in **Figure 1** below. A central element would be a Patient Advisory Panel (PAP) consisting of a limited but diverse number of patient representatives whose main task would be to

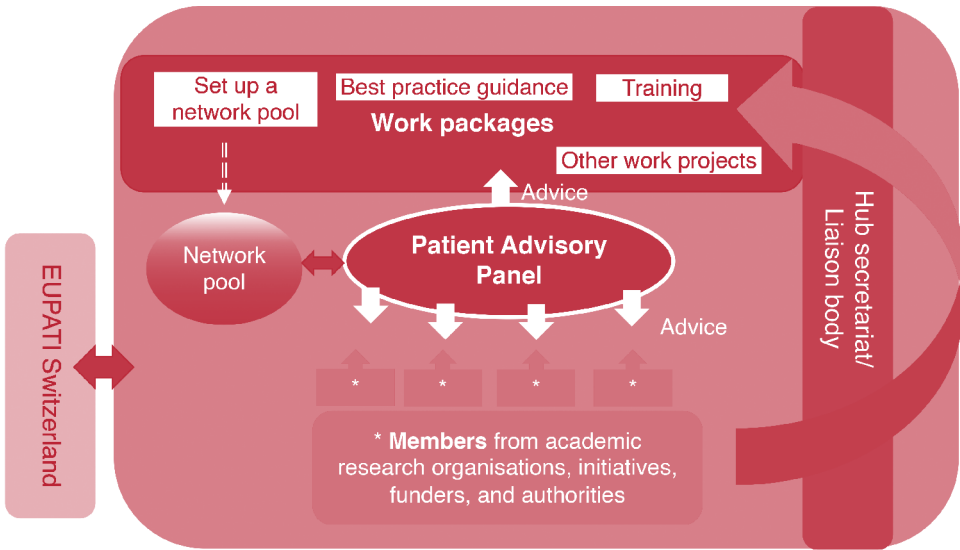
advise the hubs’ members and function as a think tank. Membership in the hub would be inclusive and open to all Swiss academic research organisations/institutions, funding bodies, and authorities with a mandate in clinical research. Specific tasks and activities, such as drafting best practice guidance or establishing a network pool of PPI contributors, could be performed in work packages and thereby co-developed by both patients (from the PAP) and hub members. The whole hub would be embedded in an appropriate governance structure, and its activities would be coordinated by an administrative secretariat or liaison body.

STILL A WAY TO GO ...

The SCTO and its CTU Network have started the process of making PPI a sustainable reality in academic clinical research in Switzerland. However, sustainable PPI cannot be achieved overnight – but rather in the long run and only

in close collaboration with our partners and stakeholders. So join us as we walk the talk and run towards our goal of embedding PPI in Swiss academic clinical research!

Figure 1: Potential set-up of the Swiss PPI Hub with its Patient Advisory Panel





# REGULATORY NEWS, EVENTS, AND PUBLICATIONS

## SWITZERLAND

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### Swiss Academy of Medical Sciences (SAMS)

#### PUBLICATION

- **JULY 2021**

#### **White Paper: Clinical Research**

What does publicly funded clinical research need in order to increase its benefit for patients and society? The Swiss Academy of Medical Sciences' White Paper: Clinical Research presents a roadmap with seven goals to strengthen the impact of clinical research in Switzerland. It suggests ways to use resources more efficiently and align efforts addressing common priorities. <sup>EN</sup>

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### Swiss Clinical Trial Organisation (SCTO)

#### PUBLICATION

- **JULY 2021**

#### **Guide for researchers that addresses patient and public involvement (PPI) in clinical trials**

Following the publication of its PPI Fact Sheet, <sup>DE, EN, FR</sup> the SCTO issued the PPI Guide for Researchers. <sup>EN</sup> This practical guide aims to help researchers who are planning a clinical research project and seeking potential funding to find appropriate ways to ensure effective and meaningful PPI in their clinical trials.

#### WEBSITE

- **JUNE 2021**

#### **SCTO Platforms' website: Tools & Resources**

The SCTO's platforms launched their user-friendly [Tools & Resources](#) website with practical tools and resources for clinical research professionals' day-to-day work. The website is continually updated and expanded with additional tools.

#### EVENT

- **JUNE 2021**

#### **10th SCTO Symposium: Medical devices: Lost in translation?**

Together with Bern University Hospital, the University of Bern, and **sitem-insel** AG (Swiss Institute for Translational and Entrepreneurial Medicine at Bern University Hospital), the SCTO held its 10th symposium on 8 June 2021 focusing on medical devices in clinical development. National and international experts shared their perspectives on the subject. Many topics were addressed during the symposium, including the new requirements for medical devices. The programme and presentation slides are available on the [SCTO's website](#).

## EUROPE

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### European Clinical Research Infrastructure Network (ECRIN)

#### WEBSITE

- **JUNE 2021**

#### **Website for coordinating European COVID-19 trials**

The [covid19trials.eu](https://covid19trials.eu) website provides a toolbox for adaptive platform trials replete with knowledge, experience, and resources from multiple projects and trials. The website's [Toolbox](#) section contains a practical guide for facilitating the planning and implementation of adaptive platform studies in all therapeutic areas.

Source: [ECRIN](#)

#### NEWS

- **JUNE 2021**

#### **ECRIN's Data Centre Certification call**

ECRIN opened its call for applications to its Data Centre Certification programme. The programme is [ISO 9001:2015 certified](#) and was developed to audit European, non-commercial data centres using [ECRIN IT/DM standards](#) in order to confirm their ability to provide compliant, effective, and efficient data management services for controlled clinical trials. Applicants had until 27 September 2021 to complete their application. Centres within ECRIN's national scientific partner networks were able to apply. Successful certification is granted for four years.

Source: [ECRIN](#)

### European Medicines Agency (EMA)

#### NEWS

- **AUGUST 2021**

#### **CTIS go-live date confirmed as 31 January 2022**

The European Commission has confirmed that the entry into application of the Clinical Trials Regulation and hence the go-live date for the Clinical Trials Information System (CTIS) will be on 31 January 2022.

Source: [EMA](#)

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### Paediatric Clinical Research Infrastructure Network (PedCRIN)

#### EVENT

- **JUNE 2021**

#### **PedCRIN final event**

The EU-funded PedCRIN project came to an end in June 2021. The final event focused on challenges in international and multicentre paediatric clinical trials and included several panels in which the setup, planning, and conduct phases of these studies was discussed and analysed. In addition, the consortium presented the project's main outcomes (supporting tools, methodologies, identified gaps, etc.) and debated future initiatives and collaborations.

Source: [ECRIN](#)

## INTERNATIONAL

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### International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

#### PUBLICATION

- **APRIL 2021**

#### **ICH GCP renovation (ICH GCP E6(R3))**

The E6(R3) working group is revising the E6(R2) Guideline “Good Clinical Practice” (GCP) with a view to addressing the application of GCP principles to the increasingly diverse trial types and data sources being employed to support regulatory and healthcare related decision-making on drugs and providing flexibility whenever appropriate to facilitate the use of technological innovations in clinical trials. Additional information may be found in ICH’s reflection paper on the GCP renovation on its [Reflection Papers web page](#).

Source: [ICH](#)

## ABBREVIATIONS

CADTH: Canadian Agency for Drugs and Technologies in Health  
CDRH: Center for Devices and Radiological Health (US)  
CHUV: Lausanne University Hospital  
CIOMS: Council for International Organizations of Medical Sciences  
COMP: Committee for Orphan Medicinal Products (EMA)  
CRC: Clinical Research Centre (Lausanne University Hospital)  
CTC: Clinical Trials Center (University Hospital Zurich)  
CTIS: Clinical Trials Information System  
CTU: clinical trial unit  
DKF: Department of Clinical Research (University Hospital Basel)  
EATG: European AIDS Treatment Group  
EATRIS: European infrastructure for translational medicine  
EC: European Commission  
ECRIN: European Clinical Research Infrastructure Network  
EMA: European Medicines Agency  
EUPATI: European Patients' Academy on Therapeutic Innovation  
EUPATI CH: European Patients' Academy on Therapeutic Innovation Switzerland  
FADP: Federal Act on Data Protection  
FDA: US Food and Drug Administration  
FOPH: Federal Office of Public Health  
GCP: good clinical practice  
HAS: Haute Autorité de Santé (France)  
HTAi: Health Technology Assessment International  
HRA: Human Research Act  
HTA: health technology assessment  
HTAi: Health Technology Assessment international  
HUG: Geneva University Hospitals  
IALP: Innovative Licensing and Access Pathway (UK)  
ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use  
IICT: investigator-initiated clinical trial  
IMI: Innovative Medicines Initiative  
ISPM: Institute of Social and Preventative Medicine  
MHRA: Medicines and Healthcare products Regulatory Agency  
NICE: National Institute for Health and Care Excellence (UK)  
NIHR: National Institute for Health Research (UK)  
OECD: Organisation for Economic Co-operation and Development  
OPBC: Oncoplastic Breast Consortium  
OrgO-HRA: Ordinance on Organisational Aspects of the Human Research Act  
PAP: Patient Advisory Panel (SCTO)  
PARTNER REC: Clinical Research Partnership Team (HUG)  
pCODR: pan-Canadian Oncology Drug Review  
PCIG: HTAi Interest Group for Patient and Citizen Involvement in HTA  
PCWP: Patients' and Consumers' Working Party (EMA)  
PCORI: Patient-Centered Outcomes Research Institute  
PED: patient experience data  
PedCRIN: Paediatric Clinical Research Infrastructure Network  
PFDD: patient-focused drug development  
PFMD: Patient Focused Medicines Development  
PRO: patient-reported outcome  
PROM: patient-reported outcome measure  
PPI: patient and public involvement  
R&D: research and development  
RAPS: Registry of All Projects in Switzerland  
RCT: randomised controlled trial  
SAFE-ID: Swiss Academic Foundation for Education in Infectious Diseases  
SAKK: Swiss Group for Clinical Cancer Research

**SAMS:** Swiss Academy of Medical Sciences

**SBP:** Swiss Biobanking Platform

**SCTO:** Swiss Clinical Trial Organisation

**SERI:** State Secretariat for Education, Research and Innovation

**sitem-insel:** Swiss Institute for Translational and Entrepreneurial Medicine (at Bern University Hospital)

**SMC:** Scottish Medicines Consortium

**SNSF:** Swiss National Science Foundation

**SPF:** Swiss Patient Forum (EUPATI CH)

**SPHN:** Swiss Personalized Health Network

**SVOI:** Swiss Osteogenesis Imperfecta Association

**swissethics:** Swiss Association of Research Ethics Committees

**Swissmedic:** Swiss Agency for Therapeutic Products

**SwissPAR:** Swiss Public Assessment Report (Swissmedic)

**USZ:** University Hospital Zurich

**WECAN:** Workgroup of European Cancer Patient Advocacy Networks

**YTCR:** Young Talents in Clinical Research (SAMS)

**ZHAW:** Zurich University of Applied Sciences



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## Sources of information

- We gather news on regulatory topics linked to human research.
- We regularly read newsletters and visit the websites of relevant sources, including regulatory authorities in Switzerland, Europe, and the USA; ICH and WHO; the major Swiss academic organisations and health associations; and professional associations.
- Additionally, we review major clinical research journals.

## Contact information

For feedback or questions regarding *Regulatory Affairs Watch*, please contact Isabelle Guilleret, Regulatory Affairs Platform Interim Coordinator: [Isabelle.Guilleret@chuv.ch](mailto:Isabelle.Guilleret@chuv.ch).

### Disclaimer

Although we do our best to ensure that all information published is correct, the publishers accept no liability for losses or damages that may arise. Always seek a second opinion before acting on information provided in this newsletter.

## Regulatory Affairs Platform

The Regulatory Affairs Platform one of the [Swiss Clinical Trial Organisation's](#) (SCTO's) eight topic-based platforms that promote excellence in clinical research in Switzerland. Find out more about the Regulatory Affairs Platform and read past issues of *Regulatory Affairs Watch* on the SCTO Platforms' [Tools & Resources](#) website.

