

NEWS FROM



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

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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, dissemin-

ation, 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.”