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 sum mary 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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