

Why and How Should Communities Be Engaged in Research & Development Processes for Safer Clinical Trials?

On September 17th, 2023, the international community celebrates World Patient Safety Day. This year, the theme is “Engaging patients for patient safety,” a rallying call to acknowledge the pivotal role patients, families, and caregivers play in ensuring the safety of healthcare practices worldwide.

The commemoration of this day, led by the World Health Organization (WHO), encourages all stakeholders in the healthcare ecosystem to listen and act. It is a clear call from patients to be included in policymaking, represented in governance structures, co-designing safety strategies, and actively participating in their own healthcare journey. This transformation can only happen if we create platforms where diverse voices from patients, families, and communities can raise concerns, expectations, and preferences to advance safety, patient-centered care, trustworthiness, and equity.

At EATG, to mark and celebrate this day we are reiterating our strong belief about the importance of engagement of patient community in the planning and implementation of clinical trials to improve patient and trial participant safety.

The importance of community involvement in clinical trials is widely acknowledged. In this regard, we can conventionally divide community involvement into two components: the first step is educating people about the advantages — and disadvantages — of participating in clinical research. Secondly, clinical trial sponsors need to be able to effectively communicate about how their work will benefit the entire community.

Moreover, the roles or tasks that community members can assume during the development of new medicines may include:

- Setting priorities and cross-cutting issues.
- Study design, planning and recruitment.
- Building bridges between authorities, researchers, and patients in the study design stage to facilitate relationships amongst important players.
- Dissemination and communication of the research process and interim or final results.
- Ensuring that the needs and confidentiality of the participants are considered during the study process.
- Supporting patients in making informed decisions about taking part in any type of clinical research by sharing first-person patient experiences.
- Presenting a personal perspective of living with a condition, identifying risk-benefit and patient-relevant added value.

Within the RBDCOV project, which EATG implements with broad participation of community members, we, as part of the Community Advisory Panel (CAP), have been actively involved in the development of research protocols. This involvement includes providing feedback on study documents shared by the research team. We do this through an internal community discussion process about risk and benefit analysis, participant safety, ethical issues, data collection methodology, and data protection. We also review questionnaires and follow-up forms, or we contribute to the drafting of participants' information materials and informed consent forms to make sure that information is accessible for the trial participants. Each CAP member can provide comments and suggestions in the form of recommendations and clarifications.

Furthermore, in the context of World Patient Safety Day, I would also like to mention that the diversity of participants and the involvement of different community members can enhance the safety and general lisability/ accessibility of trial data and the overall impact of a clinical trial. For example, the participation of people living with HIV, co-morbidities and/or other immunocompromising conditions; of people who use drugs (including people on substitution therapy), of a wider gender diverse population and of people from different age groups can broaden the scope and effectiveness of a clinical trial. Including a broader part of the population means including and representing different realities.

If community members are properly involved in the study design and planning process, the participation of different key populations will not be neglected and limited in clinical trials. I feel all these aspects were considered in the RBDCOV project to ensure that a more diverse array of participants was recruited and that targeted information for different population groups involved in the trials was made available via the website and various social media campaigns.



Finally, I would like to emphasise the importance of community participation in clinical trial communication and dissemination. Community members should be engaged in the elaboration and implementation of the dissemination strategy of research results so it can better and more

effectively reach the patient community and professional communities. Regardless of the clinical trial results, participants and the overall community should always have access and be made aware of them.

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