ORACLE

Voices to Trials

Incorporating the Patient Voice into Clinical Trials

The changing landscape

We are fortunate to be living and working in an era when policymakers, regulators, advocates, and researchers are collaborating to enhance drug development by placing a greater emphasis on patient-centered approaches and measurements that are important to a diverse group of patients.

The good news is that patients, in our experience, are also eager to share their voices and have them amplified. They understand that their voices are valuable and feel empowered by the opportunity to contribute to clinical trial design.

"No decision about me, without me" resonates with them and motivates them to participate.

Despite the emerging discussion and guidelines relating to the importance of including patient voice in clinical trial design, few case studies are documented which demonstrate ways to gain intimate insights and authentic feedback on trial requirements in a way that can impact the FDA and EMA process and optimise trial engagement.

The consequences

Creating a clinical trial that is effective and meaningful to patients and caregivers

Engaging with patients and caregivers as experts in their condition through authentic conversations and including their voices in clinical trial design, optimizes trial meaningfulness and success.

- – Patients will want to join.
- – Patients will stay engaged and complete.
- – The right patients will be represented.
- – The study will measure what matters to patients.
- – Physicians and payers will understand the value to patients.

Immersive work to generate authentic conversations.

Our **Voices to Trials** immersive work with patients is centred on building a deep understanding of the experience of living with their condition, and against that backcloth, explore how this reality affects one's ability and willingness to participate in a clinical trial.

The exploratory approach amongst patients is constructed around 2 key phases - elicitation and activation. The elicitation phase itself is further separated into 2 stages:

> **1** - The first is in-depth exploration of every day lived experiences of our target patient group to provide a rich understanding of the impact of the illness or condition: patients' challenges with day-to-day functioning, coping strategies, attitudes, beliefs, values, and needs

> **2** - The second part is where we ask participants to evaluate, again in-depth, a proposed clinical trial protocol – the findings from an understanding of their lived experience earlier in the process contextualize their reactions to the protocol design and gives them deeper meaning.

The activation phase is where we take the suggestions and recommendations from our experts – i.e. those living with the illness or condition and share them with trial specialists who review their recommendations and advise on the implications of them in terms of feasibility and optimisation of trial success.

Keeping patients' perspectives front and centre, we collate the feedback and work with our clients to recommend and prioritise amendments, where necessary, to the trial protocol that they can submit/re-submit to the regulatory authorities.

Health authorities are determined to consider the voice of the patient and have been very vocal about why this is critical, they are increasingly providing guidance on these expectations.

Optimizing trial completion

Ultimately, to optimize successful completion of a trial, a trial's design needs to resonate with all key stakeholders and patients are an important part of that mix.

Patient as expert

Patients are the experts of their illness, and if we place them firmly front and centre in order to provide a diverse population the opportunity to reflect on the experiences they've had of living with illness, to prioritise their needs, and to provide direction and feedback on the trail design itself, trials will more closely reflect their reality.

Authentic conversations

Authentic conversations with patients ensure that we delve beneath surface response and connect with what really matters to patients and consequently generate findings that will ensure that trial designs are acceptable, feasible and even desirable to patients thereby accelerating trial recruitment and optimising retention.

Measuring what matters

By ensuring we are measuring what matters to all stakeholders, including patients, we can feel confident in a comprehensive approach to trial design and the meaningful nature of the outputs generated by them.

Influence health authorities

Ultimately, the objective is to influence health authorities, so our methodologies to elicit stakeholders' perspectives on trial design, must be designed in a way that is acceptable to regulators and in the case of patients, in a way that demonstrates that they have been genuinely engaged to optimize trial success.

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