

# **Novartis Institutes for BioMedical Research Integrates Patient Insights in Early Development Trial Design and Improves Organizational Culture**

## **Novartis Institutes for BioMedical Research Applies CTTI's Patient Group Engagement Recommendations**

### **SUMMARY**

Novartis Institutes for BioMedical Research (NIBR), part of the global healthcare company Novartis, wanted to explore areas across the early clinical development spectrum where input from patient groups could be integrated to enrich its trials. Using CTTI's Patient Group Engagement recommendations as a guide, the NIBR Patient Insights and Experience Group has successfully engaged with patient groups in early development, helping the early development teams appreciate the value of the patient voice.

### **GOAL(S)**

Clinical research is one of the few industries where success is entirely dependent on individuals volunteering to participate in an investigative trial. As such, patient engagement is critical and studies must be designed thoughtfully, with the needs of the patient prioritized. Trials, after all, are ultimately for the benefit of patients and caregivers, and as such, these individuals are considered important stakeholders with a voice in the development process. NIBR wanted to optimize its patient engagement across its organization to deeply embed the patient voice into its work.

### **CHALLENGES**

NIBR is focused on early development efforts, including phase 1 and 2 trials and proof-of-concept studies, which brought unique challenges to its patient engagement activities. The patient voice is valuable at these early stages, though many of these trials do not continue on to full product development or launches. There was a perceived barrier across NIBR that the group's inability to guarantee further development of candidates would hinder its engagement efforts with patients. In addition, early development groups are science-focused by nature with limited experience communicating with and managing the expectations of patient groups. Although doing so would ultimately improve trial quality, it also represented a massive paradigm shift for employees that NIBR would have to overcome.

### **SOLUTION(S)**

The NIBR Patient Insights and Experience Group started to approach these challenges by defining specific areas of interest where they saw opportunities to bring in the patient voice across select studies. During that process, they came across CTTI's Patient Group Engagement (PGE) recommendations. As CTTI notes, patient groups can offer sponsors a wealth of insights and information, and sponsor-patient group relationships are often mutually beneficial.

### **TAKING ACTION**

CTTI's PGE recommendations reinforced for NIBR the concept of building long-term relationships with patient groups rather than interacting with them transactionally on a trial-by-trial basis. Once NIBR began getting to know how patient groups can enhance their understanding and long-term goals, it became possible to identify overlapping aims that would benefit the sponsor and the patient group alike, starting an important cultural shift across the organization. NIBR then took on its second challenge: relationship building. As a science-focused, early development team, NIBR lacked expertise in maintaining routine interactions with patient organizations. To build this muscle and facilitate relationship building, NIBR teams partnered with advocacy professionals across the Novartis organization. Additionally, the Patient Insights and Experience Group launched regular patient panels to fuel open discussions about the patient experience in a particular disease area. Importantly, those discussions were broad, extending beyond a focused conversation specific to a single trial aim. For example, Novartis has multiple programs ongoing in the Sjogren's syndrome area, so those project teams began to meet regularly with a patient group to more broadly understand their experience and how Novartis can lend support. That has led to trial awareness activities supported by the patient group, so the relationship has been a win for the Sjogren-focused patient group and Novartis alike.

To appropriately manage expectations during these discussions, NIBR engaged in transparent, early dialogue. That included sharing the exciting programs in the NIBR portfolio, but also stressing clearly that these were investigational and not guaranteed to progress. Patients interested in helping were simply supporting the opportunity for progress that may or may not come to fruition. With clear, upfront communication, expectations were better aligned, and participating patients fully understood the potential risks to the research.

These patient panels were a success, which prompted NIBR to explore new approaches to applying different methodologies for collecting patient insights across its portfolio of disease areas. These methods include desk research, surveys to patients, and more. Project teams do not apply these in a directed way hoping for specific insights, but rather as an open-ended effort to understand what patients want people to know about the patient journey. This open-ended feedback has taught NIBR project teams important insights around patient needs and preferences that have led to meaningful changes in many of the clinical studies that were conducted.

### **IMPACT**

Today, NIBR leaders see progress reflected in the organizational culture. Having seen the value of the patient voice, early development teams are less guarded about engaging patient groups. In fact, many teams proactively request patient engagement, understanding that there is real value to embedding their input. While NIBR teams once worried that patients would not want to be engaged in research that may not proceed past the early stages, they have found that patients are happy to help where they can and understand that every effort may not reap direct results.

### **ADVICE**

Culture change takes time and, like all progress, is often not a straight line. There are bumps along the way, but NIBR has

found that if you keep at it, change will happen. Although a culture shift might seem overwhelming, NIBR's leadership advises that other teams begin by simply taking a first step, such as sharing experiences and benefits. With even small changes, positive momentum can build, making future steps easier. Where there is a will, there's a way!

## **ORGANIZATION**

Novartis

## **CONTACT**

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## **ORGANIZATION TYPE**

Industry

## **IMPLEMENTATION DATE**

2018

## **TOPIC**

Patient Engagement

## **RELATED CTTI PROJECT**

[Patient Group Engagement](#)

## **CTTI RESOURCES**

[CTTI Recommendations: Effective engagement with patient groups around clinical trials](#)