

# CFF's Data Safety Monitoring Board Makes More Informed Decisions by Bringing in the Patient Opinion of What is Safe

## CFF Applies CTTI's Patient Group Engagement Recommendations

### SUMMARY

The Cystic Fibrosis Foundation's (CFF) Data Safety Monitoring Board (DSMB), which is charged with safety oversight of CFF-sanctioned clinical trials, realized it was missing a critical voice: that of the patient. Armed with CTTI's Patient Group Engagement (PGE) recommendations, the Foundation sought to make the work of the DSMB more meaningful and transparent by integrating one patient representative on to every DSMB it established.

### GOAL(S)

After a CTTI Annual Meeting, the Cystic Fibrosis Foundation's DSMB engaged in an interesting conversation. While physicians and statisticians were obviously critical members of its clinical trial DSMBs, there was an important voice missing. The groups were making decisions about what is and is not safe for patients, and yet they were not hearing the patient perspective. Wouldn't the team's effectiveness be improved if they could integrate a patient representative on each of these boards?

### CHALLENGES

The idea made sense, and everyone agreed it was the right thing to do-- however, no one on the Data Management Committee (DMC) knew how to go about it. Picking the right people to engage was one component, but the committee also had to deal with issues of confidentiality, conflicts of interest, and helping patients understand the data they would review.

### SOLUTION(S)

Fortunately, CTTI had just released its PGE recommendations and resources to help organizations understand how to best integrate patients into the research process. In addition, a few other groups such as the AIDS Network and the National Cancer Institute had implemented a similar effort. All of these offered a good starting point for the CFF DSMB to begin.

### TAKING ACTION

CFF knew it could learn from past experience, so it spent substantial time collecting existing insights on how to integrate the patient voice into its DSMB. In fact, it spent over a year connecting with individuals across the clinical trials enterprise that could offer suggestions. Through the AIDS Network, the National Cancer Institute, and other CTTI contacts, the team gleaned experiences and transferred them into its own network. Common themes emerged, including that patients often readily accepted board invitations, but then felt intimidated by the experience and were reluctant to speak up. The CFF DSMB worked in advance to avoid this challenge by educating the DSMB members to be inclusive and make specific effort to make space for patient representatives in the meetings by opening the door for questions. The DSMB developed a road map for incorporating patient representatives which included an educational component for the new members. Although Cystic Fibrosis is usually diagnosed in infancy, over fifty percent of patients are adults so it was important to recruit a representative balance of adult patients and parents (caretakers). Patient representatives are required to have a college education and experience as a participant in at least one clinical trial. The CFF began with two pilot trials, and through that process, they fine-tuned the effort and ultimately solicited applications through a CFF community patient program. Then the team conducted interviews and built its cohort.

### IMPACT

The CFF DSMB now boasts a cohort of 12 patient representatives, one of whom sits on every newly developed DMC. The vice-chair of the DSMB notes there have been several times when the patient input has been a pivotal change-maker. The addition of the patient voice to the DMCs has been a "fantastic" addition that has given insight and clarity to the CFF team's work.

### ADVICE

Integrating patients into clinical trials can seem foreign at first to both trialists and patients, both of whom may wonder how patients can truly be brought into the fold. CFF urges those with doubts to remember that not every member of a team needs to be an expert in every aspect of the work. Investigators and clinicians bring medical expertise, statisticians bring the numbers expertise, and patients bring the lived experience with the condition. Together, they can build a DSMB that looks at the study holistically and delivers better results. A final piece of advice from CFF: "It's okay to steal shamelessly from other people who have already successfully integrated patients into research! In fact, it's more than okay. It will make your effort better. If you are unsure where to start, reach out to CTTI to build connections and get the ball moving. The experiences of others are priceless in this process."

### ORGANIZATION

Cystic Fibrosis Foundation

### CONTACT

Lynne Quittell □

### ORGANIZATION TYPE

Patient

**IMPLEMENTATION DATE**

2016

**TOPIC**

Patient Engagement

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[Patient Group Engagement](#)

**CTTI RESOURCES**

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

**ADDITIONAL RESOURCES**

[A model for oversight of rare disease studies: The 25-year experience of the cystic fibrosis foundation data safety monitoring board](#)