

# CASE STUDY HIGHLIGHTS:

## Diverse Patient Engagement at a Pharmaceutical Company

Sanofi's approach to involve patients in clinical trial development

### BACKGROUND

In 2011 Sanofi acquired Genzyme, a mid-sized pharmaceutical company focused on rare diseases which routinely engaged patients in study planning and design. Appreciating that everyone with a condition, whether it's diabetes or Duchenne Muscular Dystrophy, has their own experience and narrative, Sanofi began to apply this practice to other therapeutic areas.

### APPROACH

#### Patient Advisory Panels

Sanofi identifies patients to serve on advisory panels through contracts with various patient advocacy groups. This is a key part of obtaining feedback on feasibility and design of clinical trials from the patient perspective. Participants also provide feedback through surveys that enable the company to continuously improve.

The advisory panels enable an understanding of the diversity of patients to be enrolled in the trial. Sanofi works to find patients for these panels that share demographic profiles with potential participants of an upcoming trial. In this way, study design and implementation are guided by relevant and informed perspectives reflecting the lived experience of the patients themselves.

#### **EXAMPLE: Phase 2 Breast Cancer Treatment Trial**

**Dedicated face-to-face patient panel sessions were held with the Susan G. Komen (SGK) Foundation where women with metastatic breast cancer provided feedback on study design. To ensure representative and diverse patient panels, select sessions were held for Spanish-speaking women and facilitated by a Spanish-speaking SGK patient navigator.**



**MULTI-REGIONAL  
CLINICAL TRIALS**

THE MRCT CENTER of  
BRIGHAM AND WOMEN'S HOSPITAL  
and HARVARD



## Leadership Commitment

Importantly, a multi-stakeholder team of upper and mid-level managers at Sanofi drove the effort to endorse and implement diverse patient engagement strategies.

Leaders included:

Senior VP of Scientific Platforms, R&D  
Global Head, Clinical Sciences & Operations  
Global Head, Clinical Operations Lead  
Office, Strategy & Collaboration

Head of Compliance Risk Assessment,  
Policies & Education  
Public Affairs  
Patient Advocacy Groups

## Challenges Encountered

While patient engagement is integral to Sanofi's clinical development process, implementation takes time and requires adjustments:

- Contract negotiation and relationship management with patient advocacy groups require patience, persistence, and effort.
- There was a necessary culture shift from a posture of "we cannot talk to patients or participants" to one that seeks to learn from patients, participants, and their families.
- Managing patient advisor expectations is complex when advisors are not participants in the trial upon which they are advising.



## RESULTS

Sanofi has been committed to hiring staff to focus on patient engagement, and all employees attend corporate-wide global training on how to interact with patients and patient groups.

Patient engagement has helped Sanofi simplify study designs in a number of tangible ways, including:

- reducing the number of procedures within a protocol, thus lessening patient burden
- reducing the number of required visits to the study sites and clinics
- broadening eligibility criteria, enabling greater participant access to research
- extending the dosing window from a required time to a time range, increasing flexibility and compliance
- considering logistical support mechanisms in protocols, including mobile health technologies and home administration where feasible

## CONCLUSION

Patient centricity has been identified as strategic and integral to Sanofi's culture, translating into the systematic integration of patient perspectives during study design and implementation.

It has implemented an operational patient engagement process that threads through legal review and compliance (e.g., contracting, confidentiality and privacy provisions), and clinical trial operations, and has dedicated a budget to support fair inclusion of patient input in research studies.

**For citations and more information on this case, please see the [MRCT Center toolkit](#).**