Case Study: Diverse Patient Engagement at a Pharmaceutical Company

Sanofi Genzyme's approach to involve patients in clinical trial development

Summary

In 2011 Sanofi acquired Genzyme, a mid-sized pharmaceutical company focused on rare diseases and one that routinely engaged patients in study planning and design. Appreciating that everyone with a condition, whether its diabetes or Duchenne Muscular Dystrophy, has their own experience and narrative, Sanofi began to apply this practice to other therapeutic areas, implementing Patient Advisory Panels to obtain input on aspects of planned clinical trials from the perspectives of potential participants. Sanofi has made listening to and incorporating patient perspectives a consistent practice throughout the clinical trial lifecycle. As a demonstration of its importance, Sanofi made the integration of patient perspectives into clinical projects one of Research & Development (R&D) priorities in 2019.

Approach

Patient Advisory Panels are a major component of prioritizing the patient perspective as a means to provide feedback on feasibility and design of clinical trials. Sanofi identifies the patients to serve on advisory panels through contracts with various patient advocacy groups. In addition to the panel itself, participants provide feedback through surveys enabling the company to use feedback for continuous improvement.

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

Examples of patient advisory panels

Sanofi held a series of panel sessions in 2018 and 2019 with the Susan G. Komen (SGK) Foundation to integrate perspectives of a demographically diverse patient community into the study design for a phase 2 breast cancer treatment trial. The first engagement consisted of two dedicated face-to-face patient panel sessions during which women with metastatic breast cancer provided feedback on study design. Importantly, one of the sessions was facilitated by a Spanish-speaking SGK patient navigator and held for Spanish-speaking women. Navigation programs are associated with improved breast cancer survival rates and may be especially helpful for medically underserved women who lack insurance or adequate resources to see themselves through treatment.[1]

[1] Baik SH, Gallo LC, Wells KJ. Patient navigation in breast cancer treatment and survivorship: a systematic review. Journal of Clinical Oncology. 2016 Oct 20;34(30):3686.

Leadership commitment

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 the 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; and Patient Advocacy Groups.

Successes

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. The company is 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:

> Sanofi's approach underscores that studies are designed for people in real life-- and therefore real-life input is necessary.

- 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
- consideration of logistical support mechanisms in protocols, including mobile health technologies and home administration where feasible

Sanofi exemplifies an organization that has established patient engagement as a strategic priority. 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.

Challenges

Although patient engagement is integral to Sanofi's clinical development process, implementation takes time. Contract negotiation and relationship management with patient advocacy groups requires time, persistence, and effort. Another challenge was the 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. Further, managing patient advisor expectations is complex when these advisors are not yet participants in the trial upon which they are advising. Sanofi informs members of the patient advisory panel that they will not be solicited for participation in future trials and that the investigational medication is not discussed for promotional purposes to avoid "false hope" with potential treatments.

Points to consider

- The perception and adage that sponsors cannot engage or talk to patients is false. A framework that is compliant and feasible to support patient engagement is possible.
- Contracting with patient advocacy groups provides appropriate access to the constituency to create patient advisory panels.
- Organizations can develop a collaborative approach to patient and patient organizations, providing financial and other support, including patients in the development process, and enabling the organization to understand and respond to patient needs and priorities.
- Emulating the process requires companies to confirm leadership commitment; identify responsible individuals; engage with patients and advocacy groups; provide training, reference materials (e.g., Patient Focused Drug Development guidance by FDA), and compensation to patient advisors; and plan and conduct patient and family advisory councils. Metrics of progress and of success are helpful.