How one pharmaceutical company included patient input in clinical trial development

A Case Study from Sanofi Genzyme*,*
developed with the MRCT Center

SANOFI GENZYME

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MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

The Opportunity:

Sanofi acquired the biotechnology company Genzyme, an organization focused on rare diseases that routinely engaged **patients in their work. Sanofi appreciated that such an approach might be** applicable to other diseases.

After all, everyone with a medical condition, whether it is diabetes or Muscular Duchenne Dystrophy, **has their own lived experience and story.**

Sanofi implemented **Patient Advisory Panels** to obtain input on aspects of planned clinical trials from the perspective of potential participants.

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How this is an example of health literacy in clinical research:

Engaging people comparable to the study population to gather input on the importance of the research question and the acceptability of aspects such as study design, procedures, and study materials is a health literacy best practice.

Participant centricity includes health literacy

(and vice versa)

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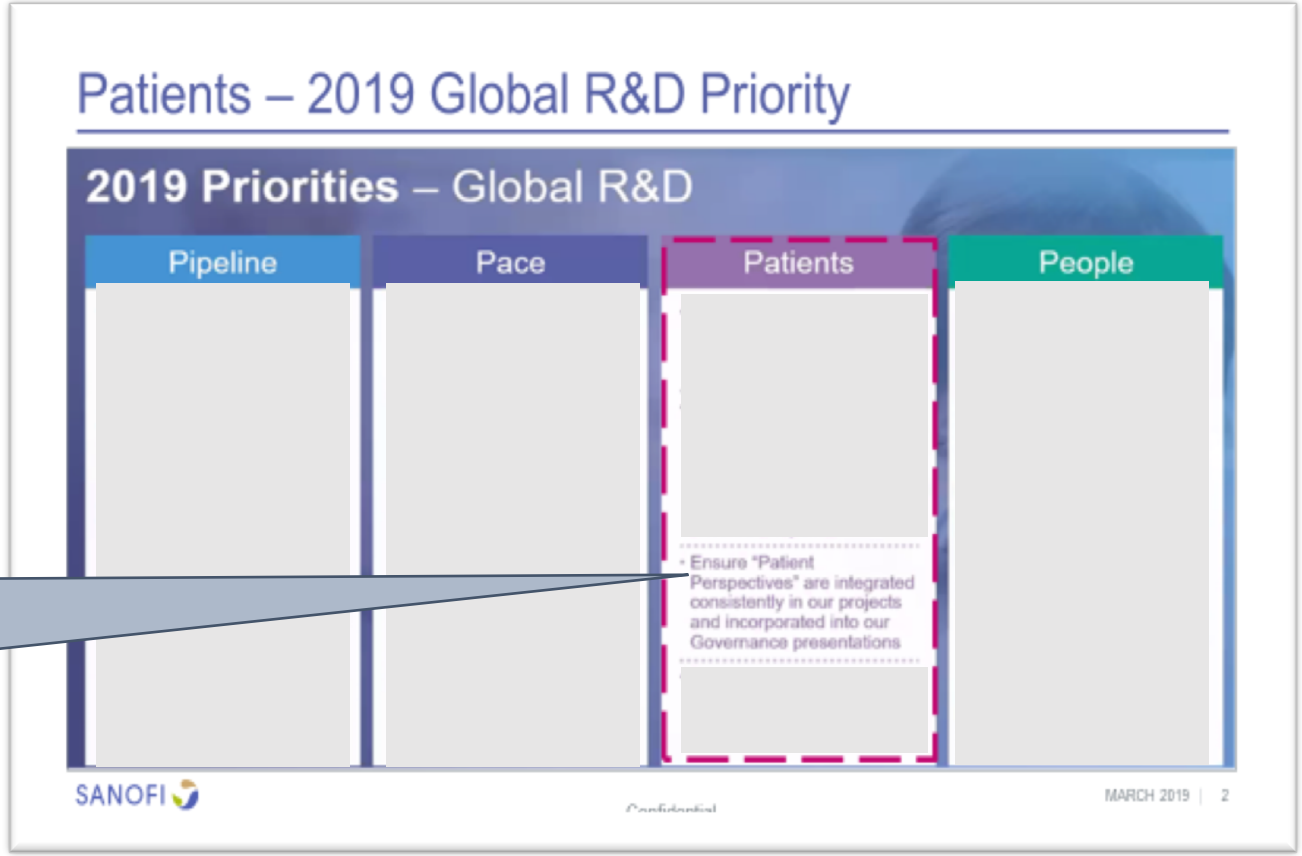
How Sanofi started working on it:

Sanofi embraced patient engagement!

- Demonstrating its importance, patients are included in the 2019 priorities for Research and Development (R&D) :

Ensure “Patient Perspectives” are integrated consistently in our projects and incorporated into our Governance presentations



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How Sanofi integrates patient input:

As part of its focus on patient priority, Sanofi runs **Patient Advisory Panels** to collect feedback on the feasibility and design of clinical trials.

Sanofi identified patients for the Patient Advisory Panels through contracts with various patient advocacy groups.

Sanofi works to find patients with profiles that **reflect the demographics of patients likely to be recruited to upcoming trials** to collect the most accurate feedback.

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Examples of Patient Questions

- What is it like to live with your condition?
  - Practically and emotionally – how does it impact your relationships, work, and quality of life?
- What benefits would you like to see from a new medication, treatment, or device?
- What factors might make it possible for someone with your condition to join a clinical trial?
  - Are the inclusion and exclusion criteria too restrictive?
- Is the planned study design overly burdensome?
- Are there too many visits or too many difficult procedures (e.g. biopsies, spinal taps)?
- What could be changed to make the study easier for patients to participate or help caregivers support trial participation (e.g. home visits, weekend appointments)
- Are there tools and technologies available to manage your condition that could be included in the study to help keep participants well-informed and engaged throughout a study?
- What is the best way to reach/inform people about this study – social media ads? Online patient communities?
- Would you be willing to review patient facing educational and recruitment materials?

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Sanofi Patient Advisory Panel Example

- Sanofi partners with the North Jersey Affiliate of the Susan G. Komen (SGK) Foundation, comprised of 9 northern counties
  - All affiliates are part of the national Susan G. Komen organization that has a broader reach and dissemination of information
  - SGK represents a diverse patient community with a focus on survivorship, diagnostic testing, support for survivors and caregivers
  - SGK includes Patient Navigators who guide patients with abnormal breast imaging results through and around the barriers in the complex cancer care system to ensure timely diagnosis and treatment.
    - 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.
- The patient engagements have consisted of:
  - Two dedicated face-to-face patient panels hosted in the Susan G. Komen offices
    - A total of 16 patients and/or co-survivors of women with metastatic breast cancer gave feedback on a Phase 2 study design
  - Additional session with Spanish-speaking only women at Trinitas Hospital in Elizabeth, NJ, facilitated by a Susan G. Komen Patient Navigator through a translator
  - Two patient panels were convened for feedback on a Phase 2 “window” study as well as a Phase 3 first line treatment study design in patients with metastatic breast cancer

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Who was involved?

A multi-stakeholder team of upper- and mid-level managers at Sanofi drove the effort to endorse and implement patient engagement strategies:

- Senior VP, 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 Advocacy (PA&A)
  - Needed PA&A early on in order to leverage the relationships that already existed with patient advocacy groups (PAGs)
  - Advised in understanding the vision, mission, and values of the respective PAGs in order to align on engagement opportunities of mutual interest

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Successes

- **Patient centricity is integral to the company culture**
  - Contributed to a culture change to a systematic and automatic expectation of patient input inclusion
  - Committed to hiring staff that focus on patient engagement
  - Corporate-wide global training on how to engage with patients/patient groups

- **Patient engagement has helped simplify study design by:**
  - Reducing the number of procedures within a protocol to lessen patient burden
  - Reducing the number of required visits to the study clinic to reduce time/family/work and school implications
  - Relaxing inclusion/exclusion criteria to enable greater access to research for more participants
  - Extending dosing window from a required time to a range to increase flexibility and thus compliance
  - Adding logistical support mechanisms including technology/health apps (e.g. home dosing) where allowable

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Challenges

- Timelines and deadlines
  - Although patient engagement is integral to the process, it takes time.
    - Building relationships with patient advocacy groups is well worth the effort
- Mindset
  - Historical perspective had been insular and concerned about compliance: “we can’t talk to patients or participants.”
    - Sanofi has shifted the focus to learning from “people with a given condition,” not from active study participants
- Managing patient advisory panel member expectations
  - Important to avoid “false hope” with potential treatments or the promise of new trial
    - 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 being discussed for promotional purposes.
    - Instead, they are told the study will be posted on ClinicalTrials.gov when it opens for enrollment.

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Feedback

- Patient Advisory Panel feedback has helped Sanofi to:
  - Develop recruitment materials and methods targeted to the desired patient population
  - Provide patients with clinical trial education in order to make an informed decision to participate or not
  - Design study-specific materials to engage and support the patient throughout the clinical trial
- Patient Advisory Panel members have found the experience empowering.
  - They report feeling that their voices are being heard.

"No one from a pharma company has ever asked us what is important to us."

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Lessons Learned

- The perception that you can't talk to a patient is not true!
  - You can build a framework that is compliant and acceptable
    - Remember: you are designing your study for people in real life and you need real life input.

- Contracting with patient advocacy groups provides access to their constituency and helps build applicable Patient Advisory Panels
  - Whenever possible compensate Patient Advisory Panel members for their input
    - Sanofi supports and pays for administrative tasks and involvement according to Fair Market Value.
    - Sanofi pays the patient advocacy group who in turn, distributes the payment to the Patient Advisory Panel members.

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Lessons Learned

- **Patient engagement is closely related to health literacy and increasing diversity in clinical trials.**
  - Sanofi Global Compliance has issued a policy addressing interactions with patients and patient groups

GLOBAL POLICY	WHERE TO FIND IT?
Interactions with Patients, Patient advocates & groups	Link
NEXT STEPS	**WHEN ?**
The head/person in charge of public affairs and the country medical chair/head at country level are responsible for implementing this Global Policy: translation, establishment of local SOP (if needed), dissemination and training	Effective date: July 3th 2018

  - Sanofi is drafting a scientific policy to address disparities in clinical trials, health literacy, and barriers in order to make clinical trials available to all.

Diversity in Human Clinical Trials - Sanofi Policy Position

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Do you want to do something similar?

- Develop a framework or methodology to guide your approach to collaboration:
  - Enlist patient and patient organization support
  - Include patients in the development process
  - Connect with the patient community
  - Assess patient needs and priorities
- Decide who in your organization should be involved in order to identify avenues for interacting with patients and start engaging specific advocacy groups (non-profits)
  - Patient and Family Advisory Councils (local hospitals and health centers)
  - Provide relevant training and reference material (e.g., Patient Focused Drug Development guidance by FDA)
- Create a process that supports legal and compliant contracting and confidentiality concerns, with a budget, if possible, to support the fair inclusion of patient input into your research studies

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Resources

Sanofi Patient Advisor Satisfaction Survey

MRCT Center Health Literacy in Clinical Research "Tools" – cultural considerations

MRCT Center Health Literacy in Clinical Research "Trial Life Cycle" – Discovery

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