The *Patients as Partners* team is proud to celebrate **Women’s History Month** by highlighting three leaders who are incorporating the patient voice into clinical trials and medicine development.

**Tammy Guld**  
Senior Director, Clinical Innovation  
Janssen

**Karlin Schroeder**  
Senior Director of  
Community Engagement  
Parkinson’s Foundation

**Jean Stimola Sposaro**  
Associate Director,  
Patient Network Management  
Sanofi
Tammy Guld  
Senior Director, Janssen Clinical Innovation

Where have you seen the patient engagement field progress to thus far since you first became involved, and where do you hope to see advancement in the next few years?

The patient engagement field has significantly evolved to ensuring the patient perspective (direct from patients themselves) is considered in decision-making. Previously, past experience and/or assumptions were leveraged to make decisions on behalf of patients. We have come a long way as an industry to give patients a seat at the table to ensure their voice is heard.

In addition, regulatory bodies have also embraced patient perspectives by getting their input into future needs within a disease area, or providing feedback on drug approvals, etc. Patients, now more than ever, have an important seat at the table.

Over the next few years, the hope is to create a clinical trial around the patient – making it easier and simpler to participate. In the age of exceptional customer service and decreasing burden, this is where the industry needs to go.

What has your organization done to increase patient involvement in clinical trials? How are you engaging with patients for meaningful and impactful change?

1). Global community advisory boards – getting feedback, understanding their needs, providing input to protocols.

2). Trial simulations – simulating our trials with patients, internal teams, and site staff to understand the “do-ability” of a protocol in actual practice.

3). Co-create solutions for needs in the advancement of patient engagement in clinical trials. We have spoken to over 1900 patients in caregivers across many therapeutic areas and around the globe to provide their perspective and input.

4). Giving patients their data back. It’s their data and providing patients their data empowers and educates them and makes them a true partner in clinical trials.

What do you see as some of the biggest barriers to involving patients as industry partners?

Despite the tremendous advances in patient involvement, there are still challenges in moving an entire industry from operating in one way to another. There is still some caution among the industry in ensuring appropriateness and level of connection with patients.

For so long in drug development, there were misperception about involving patients, there is still room to evolve. But there has been dramatic improvements in this area, which is promising and the right direction.
What impact could greater patient engagement initiatives have on your organization?

Greater patient engagement provides us as an organization another way to get it right the first time. If we can design clinical trials that better meet patients’ needs, we have the opportunity to accelerate timelines and decrease the time it takes to get these products to the market and better serve all patients, which is the goal.

We have a motto of “Better Trials. Made Together.” If each person in the organization can understand how the work that they do directly impacts patients in our clinical trials, they will think differently about how their approach to that work. Greater patient engagement affords us the opportunity to share this information with organizations and help make those linkages.

What are the areas you’ll be focusing on in 2020 (and over the next few years) for strengthening patient involvement in the drug development lifecycle?

Continuing to include patients in the co-creation of protocol design and operational solutions. Designing solutions around their needs. Providing them a forum to be ambassadors for clinical trials awareness. Getting patient feedback on their clinical trial experience. Providing information to patients in a variety of forums and vehicles.

Patients have different preferences – we need to make sure we provide more than one way to get them the information they need to make informed decisions.

**Tammy Guld** is the Senior Director, Team Leader of Janssen Clinical Innovation, which is dedicated to making clinical trials faster, less costly, and a better experience for all stakeholders.

Before joining Janssen R&D, Ms Guld spent 20 years at Bristol-Myers Squibb, where she most recently served as the Executive Director and Head of Central Clinical Planning & Solutions. In this role, she was responsible for centralized operational solutions that ensured the best trial experiences possible for patients, caregivers, and investigational sites.
Where have you seen the patient engagement field progress to thus far since you first became involved, and where do you hope to see advancement in the next few years?

When I entered the patient engagement in research space nearly ten years ago, there wasn’t any collaboration between industry partners and Parkinson’s organizations to incorporate the voice of people with Parkinson’s disease (PD) and care partners into research.

Today, there is robust interest in working together and strong success stories. I hope to see continued advancement of patient engagement into aspects of the research process where it is not as commonly occurring yet, such as in early phase development. I also look forward to more integrative models such as embedding a patient advisor in a research team over time, not just for one trial. In this model, a person with PD would join the industry team handling neurology R&D and help select therapeutic targets, develop study protocol, select sites, etc.

What do you see as some of the biggest barriers to involving patients as industry partners?

Timing is one of the biggest barriers to meaningful patient engagement. Industry and patient advocacy groups often have very different expectations as to what constitutes an appropriate contact for a partnership. It can take up to 3 months or more to create a master service agreement and scope of work everyone can agree upon. Because there is the pressure of the first patient-first visit deadline, oftentimes protocols are written during the course of contract negotiation and the window for meaningful patient engagement is closed.

The Parkinson’s Foundation has addressed these barriers by beginning conversations with industry partners early, creating template contracts and setting expectations on timelines, roles and responsibilities through a consistent, replicable methodology of patient engagement we have developed.

What do you see as the role of advocacy groups in increasing patient involvement in clinical trials?

The Parkinson’s Foundation began our work in patient engagement in research over a decade ago, bringing together researchers in academic centers, industry and government with people with PD and their care partners to increase involvement in clinical trials. While the Parkinson’s Foundation has a breadth of methods to increase involvement, two particular roles stand out.

One is preparing a representative group of people with Parkinson’s to work with research teams. For some instances of patient engagement, a partner may be seeking a person with PD who is not closely tied to a foundation and represents a lay perspective.

In other cases, a patient engagement project might benefit from involving a person with PD who understands the research process. As patient engagement pushes into different aspects of research, such as basic science or the process of patient-reported outcomes development, where writing semi-structured interview guides, running qualitative analysis of those interviews and item selection come into play, people with PD who have some technical knowledge of the process will be better prepared to provide input. It is important to note that smaller patient advocacy organizations may face capacity issues to provide training, so models of support and partnerships for those trainings are needed.
Another role in increasing patient involvement, is to actively work with industry to develop and facilitate patient engagement projects. In past surveys of research teams, the Parkinson’s Foundation found that partners were seeking guidance on patient engagement and looking for patient advocacy organizations to provide that guidance. Patient advocacy groups can share best practices, tools and resources, methodology and innovative ideas for patient engagement.

At the Parkinson’s Foundation, we work closely with our industry partners at every step of a patient engagement project to optimize obtaining patient input.

In what ways has patient involvement in industry evolved over time? What do you attribute that to?

Patient involvement has evolved from a one-and-done model where patients were brought in late in the process as a “rubber stamp” on research to a model where patients are equal decision makers in research, beginning early in the process.

I think this evolution occurred for a number of reasons. As industry, patient organizations and patients worked together, trust was gradually built; and with that, transparency and more two-way communication that made it easier to work together and made partners more open to tweaking models of engagement if partnership didn’t initially succeed.

This also led to a willingness to try patient engagement in different parts of the research process which lead to greater opportunities to work together. At the same time, organizations like PCORI and FDA put greater attention on patient engagement, giving collaborators additional incentive to work together.

What are the areas that you’d like to see advocacy and industry collaborating more on?

I’d like to see continued collaborations on developing and collecting metrics for patient engagement. Metrics are becoming increasingly sophisticated and more commonly used, but I think there is still a need for consistent metrics sets across projects.

I would also like to see ongoing collaborations for disseminating results of partnership such as co-presenting outcomes of patient engagement projects either in conferences like Patients as Partners or co-publishing journal articles. Sharing results in this way is important to advance the field.

Karlin Schroeder is the Senior Director of Community Engagement at the Parkinson’s Foundation, where she leads patient engagement initiatives. Through this program, Ms Schroeder runs the Parkinson’s Foundation Learning Institute, which trains people with Parkinson’s and their care partners in the research process and provides tools and resources for successful collaboration with research teams. Her work includes improving diversity in patient advocacy in Parkinson’s disease and defining metrics in patient engagement in research.
Where have you seen the patient engagement field progress to thus far since you first became involved, and where do you hope to see advancement in the next few years?

I think the biggest advancements have been achieved at the highest levels of organizations leading to cultural shifts in operating models. Meaning that executive level leadership are more and more acknowledging “patients” as core drivers of their business and have identified company objectives for inclusion of meaningful patient participation in the drug development process. Establishing structural frameworks, allocating resources and demonstrating a commitment to incorporating the patient in all that we do.

As a healthcare organization, we are in the business of patient care and that must remain central to our core values and business models not only through our words but in our daily operational activities and conversations.

What are the areas you’ll be focusing on in 2020 (and over the next few years) for strengthening patient involvement in the drug development lifecycle?

As we build upon our successful and evolving model in the US, we are expanding our patient network model globally. Respecting the need for diversity in clinical research and the global scope of our business, we are securing resources across the world to align best practices which are compliant with all local laws and regulations.

What do you see as some of the biggest barriers to involving patients as industry partners?

Statutory obligations to ensure the protection of patient rights and the security of their personal information (data privacy and protection legislation globally), the need for transparency and lack of trust in the research enterprise add to the complexities of partnering with patients and require that we demonstrate an open and consistent mechanism for doing so throughout the drug development and lifecycle management process.

Pressures to reduce costs and cut timelines increase the burden on project teams who will need to develop strategies that incorporate patient insights early in product planning. Coordination, sharing and aggregation of meaningful patient data and compensation of patient/caregiver advisors across R&D will require significant financial investments to ensure success and compliance and to realize the full value and impact of the patient experience in drug development, globally.

What has your organization done to increase patient involvement in clinical trials? How are you engaging with patients for meaningful and impactful change?

Patient advisors, including parents and caregivers, are part of a 3-pronged approach to our protocol optimization strategy. Working with our Public Affairs and Patient Advocacy teams, Patient Advocacy Groups and our Investigational Sites, patient advisors are identified to participate in patient advisor panels, sit on therapeutic specific or study specific patient steering committees or respond to focused surveys about our early and ongoing clinical trial planning, including providing meaningful input into protocol design, informed consent documents and other educational materials.

Patient advisors are required to sign a mutual confidentiality agreement if they choose to participate in these activities and are free to stop participating at any time.

To ensure that we are meeting the needs of our patient advisors and to continue to improve our ways of working with them we offer an opportunity for them to anonymously provide feedback about their experience as an advisor.

Patient advisor panels are conducted either virtually or face to face. Some advisor panels
are conducted with a single advisor, others are conducted with a group of patients with the same condition. Patient advisors may be trial naïve or may have previously participated in a clinical trial. The intent of the involvement of patient advisors is NOT to recruit patients for any of our clinical trials or to promote the investigational product, in any way.

The feedback that we received during our advisor panels were scientifically plausible and used to directly modify early study design, decisions related to frequency and type of “required” study procedures, and tools to be used during the study in advance of finalizing the protocol.

To reduce patient (study participant) burden, we have simplified study designs by:
• Reducing the number of procedures within a protocol lessens patient burden
• Reducing the number of required visits to the study clinic reduces time/family/work and school implications
• Relaxing inclusion/exclusion criteria enables greater access for more patients to receive treatment
• Extending dosing window from a required time to a range increased flexibility/compliance
• Modifying biopsy requirements to include archived samples where scientifically feasible reduced impact of frequent stressful invasive procedures
• Adding logistical support mechanisms allows for technology/health apps; home dosing, where allowable
• Reducing the number of overly burdensome patient reported outcome (PRO) measures increased compliance

Patient feedback has also helped us to:
• Develop recruitment materials and methods targeted towards the desired patient profile
• Provide patients with clinical trial education in order to make an informed decision to participate or not in clinical research
• Design study-specific materials to engage and support the patient along the clinical trial experience
• Better understand the unmet needs and unforeseen disease burdens of patients and their caregivers
• Develop endpoints that matter most to patients
• Make decisions about product formulation and delivery which help to reduce burden and improve adherence

What impact could greater patient engagement initiatives have on your organization?

Executing and sustaining meaningful patient partnerships across the product lifecycle demonstrates our long-term commitment to a cultural shift in the way we think about drug development strategies and may help to improve a patients’ ability to be true shared decision makers in their healthcare. In helping patients understand the medical and clinical rationale for drug development and the requirements for continuous monitoring and evaluation we can include them in the decisions we make about our product development and risk management strategies and learn more about patient acceptability of benefit vs. risks in their decision making.

By bringing patients into the process, we are increasing awareness about clinical research and are removing some of the mystery and stigma behind the curtain and can hopefully begin to improve the image and reputation of drug developers. Importantly, by designing clinical trials and treatments that matter most to patients, we hope to reduce the time it takes to bring those treatments to market.

Jean Stimola-Sposaro is the Associate Director of the Patient Engagement Network at Sanofi.

In that role, she collaborates across the organization to champion new operational processes designed to ensure that the voices of patients, caregivers and study participants are consistently incorporated into early protocol design and cross-program strategies throughout the product lifecycle.

New Patients as Partners US dates:
June 29-30, 2020
Hilton Philadelphia at Penn’s Landing, Philadelphia, PA

Produced by Danny McCarthy