6TH ANNUAL

PATIENTS AS PARTNERS US

MARCH 11-12, 2019 | WYNDHAM PHILADELPHIA HISTORIC DISTRICT, PHILADELPHIA, PA

Turning Discussion Into Action: Applying Patient Engagement Initiatives and Demonstrating Impact

Featured Speakers

Suzanne Schrandt, JD
Arthritis Foundation

Craig Lipset, MBA
Pfizer

Patricia Marinello, PharmD
Merck Research Labs

Julian Jenkins, PhD
GSK

Pan Patel
Celgene

Elise Felicione, MPH, MBA
Scripps Research Translational Institute / Janssen R&D

Cindy Geoghegan
Patient Advocate

Sarah Larson
Biogen

Anindita Saha
CDRH, FDA

Robert Long
Patient Advocate

Robert Weker, MBA
Patient Advocate

Beth Zaharoff
Tesaro

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GLOBALCARE CLINICAL TRIALS

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DAY ONE - MONDAY, MARCH 11, 2019

7:45 am
Registration & Breakfast

8:30 am
Co-Chairs' Opening Remarks: Demonstrating the Impact of Patient Engagement
As part of opening remarks, Suzanne Schrandt will share her experience working with an esteemed research organization on a patient engagement effort that involves patients to obtain feedback on research proposals. This talk will address the following:

- Evaluation of the original patient engagement request and why it was the wrong approach
- What needed to change with the approach in order to get the most out of the patient feedback?
- A Step-by-step guide on how Suzanne Schrandt worked with researchers to uncover what they wanted to get out of the patient's review
- Brief introduction to the onsite mock clinical trial exercise on day one

Suzanne Schrandt, JD
Director, Patient Engagement, **Arthritis Foundation**

8:50 am
Keynote on Patient Centricity
This session provides an insight into leadership and culture that is needed to drive patient-centered drug development. Learn what everyone in the organization can do to influence patient-centricity.

9:20 am
Chief Patient Officer Roundtable: Driving Culture Change from the Top Down

- How do you create a culture that enables new strategic, operating and organizational models to flourish?
- How do you drive a patient-centric organization while continuing to execute on business imperatives? How do you balance that?
- How do you drive a patient-centric agenda through the value chain?
- How do you engage your employees and empower them to implement patient involvement strategies? And, how do you enlarge the outlook of employees who are stuck in status quo?

10:00 am
Morning Networking Break

10:40 am
Mapping Out the Patient Decision Journey
If we truly want to bring patients in as stakeholders, we have to start at the beginning by understanding patients, their lifestyles and how the trial protocols are developed to reflect that. Furthermore, we need to better understand the decision making process a patient goes through when considering their treatment options, including clinical trial participation. Understanding these dynamics will help industry design appropriate initiatives that help meet its goals while aligning with patient's needs. This session addresses:

- What can we learn and what resources can we use to develop a baseline understanding of patient lifestyles?
- What can sponsors do throughout trial protocols that can help support patients, help alleviate their worries/concerns?
- What is the decision making process a patient goes through when considering treatment options?
- What do patients consider when determining to participate/not participate in a clinical trial?
- How can pharma help support/provide tools that will help patients while deciding which treatment pathway they choose?
- How can advocacy groups support this and how do they help inform patients?

11:20 am
PHARMA & BIOTECH CASE STUDIES: APPLYING PATIENT ENGAGEMENT INITIATIVES AND DEMONSTRATING IMPACT
Attendees have a choice of six case studies to choose from where pharma and biotechs share tangible examples of how patients were involved in clinical development and trial initiatives, how they implemented patient input, challenges faced and the outcomes to the initiatives as a result of including patients.
Companies to date include:

- Merck Research Labs
- GlaxoSmithKline
- Takeda Pharmaceuticals
- Additional Companies TBD

12:30 pm
Lunch & Birds of Feather Roundtable Discussions

1. **Building Patient Engagement into Systematic Processes**
   - How do we look at patient engagement like we look at quality interventions?
   - How do we build patients into our systematic process?
2. **Online Communities & Social Media**
   - How can sponsors better use social media to educate patients about clinical trials? What are their concerns and how can we address them?
   - How can sponsors build trust with patients so they can obtain honest patient feedback in sponsor-led online trial communities?
   - How social listening can be leveraged to optimize clinical trials
3. **Connecting Employee Centric Culture to Patient Centric Culture**
   - How do you engage your employees and empower them to implement patient involvement strategies?
4. **Pharma/Advocacy Partnerships**
   - What are the steps to creating a pharma/advocacy partnership?
   - Examples of successful industry advocacy partnerships and the impact
5. **New Ways to Overcome Recruitment Challenges**
   - What are the ongoing recruitment challenges the industry has been unable to solve to date?
   - Are sponsors/sites/recruitment providers using the right technology to reach specific patient populations?
6. **Site Selection**
   - How site selection impacts patient optimization
7. **Technology and Digital Health**
   - How technology is having an impact on the clinical trial experience for patients and investigators

1:30 pm
Annual Keynote by Ken Getz, Tufts CSDD
Ken Getz, MBA
Director of Sponsored Research Programs, **Tufts CSDD**

1:55 pm
Panel: Partnering With CROs/Sites to Create a Delightful Patient Experience Starting with Engagement
As we know, most studies are outsourced to CROs/Sites and many of these partners have made serious investments towards greatly improving patient engagement capabilities This panel will discuss how sponsors and sites are advancing their work to excel at patient engagement to create greater efficiencies and better outcomes for patients. More specifically:

- How do you build patient engagement into your Sponsor/CRO policy and procedures?
- What should that partnership look like?
- How can CROs and advocacy better work together and what is the ROE for working together?
- Examples of positive relationships between CROs and advocacy groups

2:40 pm
GlobalCare Clinical Trials Case Study

2:55 pm
Afternoon Networking Break

4:10 pm - 5:30 pm
Afternoon Breakout Sessions

TRACK: PATIENT DATA & RETURNING RESULTS Moderated by: **Craig Lipset, MBA**, *Head of Clinical Innovation*, **Pfizer**	
4:10 pm	**The Democratization of Patient Data Ownership: Returning Results** We anticipate a future with secure patient data ownership, where patients are empowered to provide permissions. In this series of talks on patients 'donating' data, patient data ownership, data rights, and why this is a disruptive force in advancing clinical trials, we address the need to ensure we have the appropriate systems, security, and ability to withstand a Facebook/ Cambridge Analytica scenario. **Craig Lipset, MBA**, *Head of Clinical Innovation*, **Pfizer**
4:15 pm	**Patient Perspective on Patient Data Access, Control, Ownership & Non-health Data** **Bray Patrick-Lake, MFS**, *Director of Stakeholder Engagement*, **Duke Clinical Research Institute**
4:35 pm	**Technology & Policy Supports for Patients to Access and Control their Data**

4:50 pm	**Panel: How to Return Data to Patients and Inform Patients Throughout Trials**
	• What data is important to patients and when? How can sponsors/sites provide data throughout the ongoing trial? Such as:
	  • How enrollment is going?
	  • What data can be shared that is relevant to where they are in the trial?
	  • How do we capture the patient experience throughout a trial?
	• How do you work with patients to make sure we are disseminating the information that is important to them?
	• How do patients want to receive their data and how can they track it for their personal use?
	• How do we close the gap and return data to patients in real-time opposed to 6-9 months post trial?
	• Can real-time data readouts be harmful to patients? Is there room for misinterpretation and misguided actions?
	• How can we better develop the delivery of patient data? [ie: Investigator portals versus traditional word documents
	Craig Lipset, MBA, *Head of Clinical Innovation*, **Pfizer**
	Jessica Scott, MD, JD, *Head of R&D Patient Engagement,* **Takeda**

TRACK: TECHNOLOGY & DIGITAL HEALTH	
4:15 pm	**Aligning Technology with the Patient Voice** • How do we identify shared value for both pharma and patients? • Patient perspective on being monitored continuously • What data is appropriate to share? • Pharma perceptions of what patients want versus what patients really want
4:45 pm	**Site-Less Trials: A Direct-to-Patient Approach** A direct-to-patient model (or site-less/remote trial) allows patients to participate in clinical trials from their home. Depending on the complexity of the trial, patients may take medicines themselves or rely on a home healthcare nurse for support. This type of model reduces the burden on patients having to travel to investigator sites and increases trial participation and retention. Additionally, technologies, such wearable, sensors and other mHealth/digital technologies play an important role in collecting data, monitoring health throughout the trial and enabling patients to complete assessments that would typically occur in the clinic. This panel addresses: • How do you directly engage with patients in a site-less or remote trial? • Technologies and services that aid in creating greater efficiencies throughout the site-less trial • How site-less trials are reinventing clinical trials and the impact it has on pharma and the outcomes for patients

5:30 pm
6th Annual Networking Reception

DAY TWO - TUESDAY, MARCH 12, 2019

8:00 am
Registration & Breakfast

8:30 am
Co-Chairs' Opening Remarks
Suzanne Schrandt, JD
Director, Patient Engagement, **Arthritis Foundation**

8:40 am
Keynote: How We Can Collaborate as an Industry to Reduce Friction Points and Deliver Value to Patients

9:05 am
New Agency Efforts to Advance the Patient Voice in Medical Product Development and FDA Regulatory Decision-Making
This talk will address the draft guidance released October 2018 on Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.

9:30 am
FDA Guidance on Collecting and Submitting Patient Experience Data & an Update on How to Use Patient Preference Studies towards Approvals

9:50 am
Morning Networking Break

10:35 am
FDA Patient Engagement Synergistic Efforts
This multi-center FDA panel focuses on patient engagement and regulatory decision making.

- What is each center doing in terms of patient engagement? What initiatives are underway and what is the impact they will have?
- What are the synergistic efforts across the FDA centers?
- How are the patient involvement initiatives within the FDA moving the needle forward in order to create greater efficiencies and better outcomes for patients?

11:15 am
Case Study: ALL OF US Initiative
All Of Us is a US Precision Medicine program from the NIH that aims to enroll a million Americans and follow them for 10 years, during which time participants will contribute biological, environmental, and lifestyle data that will help accelerate research and improve health. Furthermore, the data will be returned to trial participants. Learning objectives:

- About *All Of Us* – context, objectives, progress to date, and what's to come
- What we've learned so far
- How might pharmaceutical companies become involved in the years ahead?

11:30 am
Panel: Diversity and Reaching the Unreachable Patients

- Is advocacy engaging on the community level? If so, how?
- Are advocacy groups reaching the unreachable patient and what can industry do to help?
- What is advocacy doing in this space that industry can learn from?
- There is still a good percentage of patients that do not have internet access, so how are you enrolling patients? Are you electronically enrolling or giving patients a paper option?

12:05 pm
How Might Biopharma Help Patients Become Knowledgeable Partners
To have a real impact on the pipeline of new treatments, patients, advocates, and care partners need to learn the language, norms, roles, constraints, regulations, and politics of Biopharma R&D. There appears to be real need in the US to provide consistent, high quality education for patients who want to get involved and bring their A-game.

Industry is not well positioned to provide this education directly without the appearance of undue influence. Likewise, very few Patient Advocate Organizations have the resources to fund the development and delivery of such education alone.
This talk will discuss:

- The value of equipping patients with the knowledge, skills, and confidence to be strong partners,
- Challenges of investing in effective patient education not connected to a product or company
- Creative ways to overcome this conundrum.

Kevin Freiert, MBA
Owner and Principal, **Salem Oaks**

12:25 pm
Lunch

1:25 pm
The TransCelerate Patient Experience Initiative: New Tools to Enable and Encourage a More Systemic Partnering with Patients in the Development of New Therapeutics
The TransCelerate Patient Experience (PE) Initiative has a vision to increase engagement and partnership between sponsors and patients and to create better experiences for clinical study participants. The PE team is developing two toolkits with the following goals – 1) to help sponsors better partner and collaborate with patients during study design and 2) to assist sponsors in collecting patient feedback while patients are enrolled and participating in clinical studies. These toolkits, have been developed by understanding study participant experiences using established clinical outcomes assessment (COA) methodology and feedback from various stakeholder groups (i.e., patient advisors, sites, CROs and sponsors). The toolkits include a sponsor-facing user guide, which is intended to support sponsors with operationalizing the tools in a clinical study. This interactive web-based interface will launch in early 2019 and will be open to the public. In this session, Stephen Yates, head of TransCelerate's Patient Experience Working Group, walks the audience through new tools that provide step-by-step considerations on how to involve patients in the medicines development lifecycle.
Stephen Yates
Global Clinical Development & Medical Affairs / Head, Patient Engagement Working Group, **UCB / TransCelerate**

1:40 pm

Panel: Partnering with Patients for Medical Device R&D

What are the unique needs of the medical device industry when it comes to partnering with patients?

Where are medical device companies at in the journey of patient engagement? What is getting in their way? What does the end of the race look like for them?

Patient Perspectives: Patients talk about how they are working with the medical device industry

Led by:

Stephanie Christopher

Program Director, **Medical Device Innovation Consortium**

2:20 pm

Integrating Clinical Research as an Alternative Care Source

In this two-part session, we hear from patients on what they are really up against when it comes to clinical research as a care option. Following the patient-led discussion, we are joined by physicians and researchers to learn more about how they can partner to better inform patients on clinical research and trial participation.

1. **What Is the Patient Really Up Against?**
   - Identifying barriers
   - How do patients get access to clinical trials?
   - Reimbursement
   - Need for interoperability and "fit for purpose" health data to enable research that benefits patients
   - Awareness of clinical trials
2. **Researcher/Physician Panel: Better Partnering Strategies to Inform Patients on Clinical Research and Trial Participation**
   - Demystifying physician/research burdens
   - How to better inform physicians of clinical research and trials
   - How to ensure patients who are treated at rural community doctor facilities are still getting the same standard of care as the centers of excellence

3:20 pm

Conference Concludes