7TH ANNUAL

PATIENTS AS PARTNERS US

MARCH 16-17, 2020 • HILTON PHILADELPHIA AT PENNS' LANDING, PHILADELPHIA, PA

Bringing Value Back to Patients: Applying Patient Engagement Initiatives and Demonstrating Impact

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DAY ONE - MONDAY, MARCH 16, 2020

7:45 am
Registration & Coffee/Tea

8:15 am
Co-Chair's Opening Remarks
Jamie Troil Goldfarb
Cancer Veteran & Advocate

Marilyn Metcalf, PhD
Senior Director, Patient Focused Development, Global Medical, **GSK**

Pablo Graiver
VP, Patient Engagement Digital Strategy Leader, Design & Delivery Innovation, **IQVIA**

PATIENT KEYNOTE

8:30 am
The Patient View: Biogen/Eisai Alzheimer's Trial Participant Jeff Borghoff's Insights into His Experience of a Failed Trial
We are honored to open Patients as Partners with Jeff Borghoff who in this fireside chat, provides personal insights on his patient experience and lessons for all of us.
Jeff Borghoff
Alzheimer's Patient Advocate

INDUSTRY KEYNOTE

8:50 am
Johnson & Johnson's Chief Medical Officer's Perspective on Making the Patient Experience Central to Business Strategy and Purpose
J&J's CMO, Dr Waldstreicher will share tangible examples from Johnson & Johnson on how the company keeps patients at the center of all decision-making.

- **The Office of the Chief Medical Officer (OCMO):** The impetus for why Joanne created the OCMO, its role across all three sectors of J&J, the company's approach to medical safety and examples demonstrating impact for patients and how J&J keeps them at the center of all decision-making
- **Healthcare is undergoing change:** Joanne will set the stage to explain the current healthcare landscape
- **YODA Project:** J&J's approach to sharing our clinical trial data with researchers around the world through transparent data sharing to advance patient health outcomes
- **Incorporating a patient-centric approach:** Highlight benefit-risk assessment examples, integrating the patient experience into clinical trials and working collaboratively with regulators to refine policies and incorporate diverse patient perspectives that represent multiple populations
- **CompAC:** Inspired by J&J's commitment to patients and the very sensitive bioethical challenge of compassionate use requests, Joanne will highlight J&J's work with NYU to develop an approach for reviewing requests for Janssen's investigational medicines in a consistent, transparent and equitable manner that incorporates the patient voice

Joanne Waldstreicher, MD
Chief Medical Officer, **Johnson & Johnson**

CUSTOMER SERVICE GURU KEYNOTE

9:20 am
Service and Patients: What We Can Learn From the Service Industry To Bring Value Back to Patients
Service industry guru, Dr Chip Bell is a world-renowned authority on customer loyalty and innovative service. In 2019, Global Gurus ranked him in the top three keynote speakers in the world on customer service for the fifth straight year in a row. Dr Bell joins Patients as Partners for the first time to tell us how to think like a service industry and be influential as an agent of change. Dr Bell provides tangible examples on what we can learn from the service industry by changing our culture to support service-oriented thinking that brings value back to patients.
Chip Bell, PhD
Customer Service Guru

10:00 am
Grand Opening of the Patients as Partners Café & Networking Break

- Breakfast
- Meet the Exhibitors
- Ask the Patients
- Networking

ANNUAL KEYNOTE ADDRESS

10:45 am
New Data on Patient Preferences and Experiences to Inform Patient Engagement Strategies and Tactics
Ken Getz, MBA
Director and Associate Professor, **Tufts CSDD** / *Founder and Board Chair,* **CISCRP**

11:15 am

The View @PatientsasPartnersUS

We are delighted to introduce "The View at Patients as Partners", which provides an interactive format set up as an interview segment for presenting organizations and the audience.

Hosts:

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

Jessica Scott, MD, JD
Head of R&D Patient Engagement, **Takeda**

Jamie Troil Goldfarb
Cancer Veteran & Advocate

Taren Grom
Founding Partner/Editor, **PharmaVOICE**

Guest Companies:
WCG

IQVIA

parexel

12:00 pm

Lunch & Birds of a Feather Roundtable Discussions @PatientsasPartnersUS

Birds of a Feather roundtables provide a gathering place for informal discussions around topics of interest. Each table will have a moderator leading the discussion and will include a patient representative who will provide their insight to the topic at hand.

Birds of a Feather Discussions Include:

- **Promoting Clinical Trial Awareness to Physicians, Patients and Caregivers of Clinical Trials**
  - Update on current efforts
  - Opportunities to collaborate
  - Urgent needs
- **Deciding Which Patient Engagement Activities to Do Based on Limited Resources**
  - How do you decide where to allocate your limited patient engagement resources (ie: which projects/compounds/ indications). Where will you gain the most?
  - How do you determine if the value worth the investment of time and resources?
- **Additional Topics TBD**

1:00 - 2:00 pm
Track Choices for Patient Engagement Innovative Sources & Solutions

We have seen a really nice evolution in companies that are enabling many new capabilities that can radically improve clinical trial efficiencies and the patient experience. This section of the program will include service companies to present on what they are specifically solving to advance clinical trials, increase efficiencies and reduce the burden to patients and investigators. Attendees are free to choose among the following tracks:

TRACK A: Recruiting & Retention	TRACK B: Data & Technology	TRACK C: Where are they Now?

2:00 - 3:15 pm
Track Choices for Case Studies: Applying Patient Engagement Initiatives and Demonstrating Impact

Attendees have a choice of nine case studies to choose from where biotech and pharma companies along with advocacy and regulatory 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.

TRACK A: Biotech Patient Engagement Initiatives	TRACK B: Advocacy & Regulatory Patient Engagement Initiatives	TRACK C: Pharma Patient Engagement Progress & Lessons Learned

TRACK A: Biotech Patient Engagement Initiatives

2:05 - 2:25 pm

Operationalizing Patient Engagement Throughout the Drug Development Process From an Early Stage Biotech Perspective

In this session, Christeen Moburg, Head of Patient Advocacy for Sangamo Pharmaceuticals walks the audience through how Sangamo implemented patient engagement in early phases of development, what that process entailed and case examples of impact.

Christeen Moburg

Head of Patient Advocacy, **Sangamo Pharmaceuticals**

2:25 - 2:30 pm - Optional Track Change

2:30 - 2:50 pm

Biogen's Patient Engagement Training Program For Early Drug Discovery That has Captured Endpoints Meaningful to Patients

In this session, Jessica Riviera, Senior Director, Global Patient Advocacy for Biogen, shares with the audience how Biogen developed a patient engagement training program for their early drug discovery team that addresses the following:

- What does patient perspective mean?
- How do you capture the patient perspective?
- What are some of the instruments/tools you can use to capture that information in a robust way both quantitatively and qualitatively?
- How do we shift the paradigm so that when you are working to develop a clinical trial, you have developed endpoints that are meaningful to the patient?

Jessica Riviere

Senior Director, Global Patient Advocacy, **Biogen**

2:50 - 2:55 pm - Optional Track Change

2:55 - 3:15 pm

Ultragenyx Case Study

Kim Cohee, *Director, Patient Advocacy*, **Ultragenyx**

3:15 - 3:45 pm - Afternoon Networking Break

TRACK B: Advocacy & Regulatory Patient Engagement Initiatives

2:05 - 2:25 pm

A New Paradigm of Patient Engagement in Research: International Collaborations between Sponsors and Patient Advocacy Organizations

In 2018, UCB, the Parkinson's Foundation and Parkinson's UK began a multi-year international collaboration to work together with people affected by Parkinson's on clinical outcomes assessment research. A research team was brought together to plan and execute a UCB project focused on patient reported outcomes tools. As a result, a successful model of patient engagement in research through international collaboration utilizing combined inter-organizational expertise was developed. This model can improve clinical trials at a global level, bringing us closer to the goal of finding a cure and better treatments for patients. In this session, UCB and the Parkinson's Foundation will present their model of collaboration, including methodology and metrics, successes and challenges and outcomes of their work together.

Karlin Schroeder

Senior Director, Community Engagement, **Parkinson's Foundation**

Speaker TBD, **UCB**

2:25 - 2:30 pm - Optional Track Change

2:30 - 2:50 pm

Medical Device Collaborative Communities: What We Can Learn & Apply to Patient Involvement for R&D in Medicines Development

In the medical device ecosystem, collaborative communities bring together stakeholders to work together on medical device challenges to achieve common objectives and outcomes. CDRH believes collaborative communities can contribute to improvements in areas affecting patients and healthcare in the United States.

In this session, Dr Michelle Tarver, Director of Patient Science & Engagement and leading the collaborative community effort at CDRH walks the audience through what the community is, what can we learn from it, how can we implement a similar initiative for medicines development R&D and the impact it can have for all stakeholders by creating such a community.

Michelle Tarver, MD, PhD

Director of Patient Science & Engagement, **Center for Devices and Radiological Health (CDRH), FDA**

2:50 - 2:55 pm - Optional Track Change

2:55 - 3:15 pm

Partnering with Advocacy to Help Patients with Clinical Trial Enrollment, Disease Education and Access to Treatments

In this session, Alnylam and the American Porphyria Foundation (APF) share how they collaborated and the process behind ensuring that patient needs were taken into consideration when designing the Alnylam's Phase 3 study. They partnered together on disease awareness efforts to go

over the eligibility criteria for the clinical program, and also collaborated on creating educational materials that were user-friendly for doctors and patients. Further, APF Identified and shared potential barriers to access with Alnylam prior to commercialization of givosiran, allowing Alnylam to provide more customized patient resources to help patients understand their treatment options. Together they delve into how they have involved patients in clinical trial design and recruitment including:

- How together, they identified patients and caregivers for an advisory board for a Phase 3 design that led to the trial over enrolled and enrolled quicker than expected.
- How the pharma/advocacy collaboration was critical to disseminating information about the trial and providing anonymous feedback on patient experience.
- How they collaborated on patient-reported outcomes (PROs) study, which was instrumental to Phase 3 design.

Barry Greene
President, **Alnylam Pharmaceuticals**

Desiree Lyon
Co-Founder and Executive Director, **American Porphyria Foundation (APF)**

3:15 - 3:45 pm - Afternoon Networking Break

TRACK C: Pharma Patient Engagement Progress & Lessons Learned

2:05 - 2:25 pm
How Patients Changed the Course of Inclusion/ Exclusion Criteria Across all Sanofi Oncology Clinical Trials That Require Biopsies
Jean Stimola-Sposaro
Associate Director, Patient Network Management, **Sanofi**

2:25 - 2:30 pm - Optional Track Change

2:30 - 2:50 pm
Janssen's Direct-to-Patient Trial Approach: Progress and Lessons Learned
Tammy Guld
Senior Director, Janssen Clinical Innovation, **Janssen**

2:50 - 2:55 pm - Optional Track Change

2:55 - 3:15 pm
Update on Patient Engagement Initiatives and Their Impact from BMS
Pan Patel
Director, Clinical Trial Patient Advocacy, **BMS**

3:15 - 3:45 pm - Afternoon Networking Break

3:45 - 6:00 pm
Three Afternoon Breakout Choices

TRACK A: PATIENT DATA & METRICS	TRACK B: VIRTUAL TRIALS & SITE / CRO COLLABORATIONS	TRACK C: DIVERSITY & INCLUSION

TRACK A: PATIENT DATA & METRICS

3:45 - 4:05 pm
Patient Data Access Initiative: A Multi-Pharma Collaboration on Returning Data to Patients
Pfizer, Janssen, Takeda and BMS joined forces to co-create the Patient Data Access Initiative (PDAI) that will provide an industry standard that is focused on returning clinical trial data to patients. The four pharma groups join Patients as Partners to share the PDAI objectives, progress and impact it will have on patients and all patient engagement stakeholders.
Vivian (Cheng) Larsen, MBA
Associate Director, R&D Patient Engagement, **Takeda**

David Leventhal, MBA
Senior Director, Clinical Trial Experience, **Pfizer**

Megan McBride, MPH
Associate Director, Janssen Clinical Innovation, **Janssen**

Jennifer Ribeiro
Informed Consent Process Lead, Global Clinical Documentation & Submissions, Global Clinical Operations, **BMS**

4:05 - 4:45 pm
Panel: Progress on Patient Data Ownership Initiatives
Patients wanting to own their data that has been collected in clinical trials is not a new concept, however, the challenge of how to actually do this still exists. This panel will focus on the following:

- The progress of returning data to patients - where are organizations today with this initiative?
- Who is succeeding in this area and why?
- What to do to get other organizations on the bandwagon?
- Empowering patients by giving access to their data that can help:
  - Drive their quality of care
  - Educate them about their disease
  - Direct care team in ways that are meaningful beyond medical outcomes and more on quality of life
- Patient perspectives on what data matters the most to them and why

Led by:
Vivian (Cheng) Larsen, MBA
Associate Director, R&D Patient Engagement, **Takeda**
with
David Leventhal, MBA
Senior Director, Clinical Trial Experience, **Pfizer**

TRACK A: PATIENT DATA & METRICS

4:45 - 5:05 pm

How Investing in Patient Engagement Activities Brings Value Back to Patients: A Takeda Case Study

In this session, Jessica Scott, Head of R&D Patient Engagement, Takeda shares the metrics and performance indicators that Takeda uses to demonstrate the value of patient engagement activities. Additional areas of discussion include:

- Hows as a result of KPIs designed to support patient engagement activities across the organization has created a culture change and has deeply demonstrated the value of engaging with patients.
- Qualitative patient engagement metrics that impacted operational change and case examples (ie: primary endpoints) and how those impacts were measured based on value.

Jessica Scott, MD, JD
Head of R&D Patient Engagement, **Takeda**

5:05 - 5:45 pm

Measuring the Impact of Patient Engagement Throughout Drug Development Panel

- What and how are we measuring engagement?
- What are the metrics and performance indicators that demonstrate return on engagement (ROE) of patient centric initiatives
- How can we measure the effectiveness of our efforts for both patient outcomes and industry and regulatory decision-makers?
- Are the metrics only applicable to the individual indication or can it be applied to future studies/indications?
- Are simpler metrics such as the number of times you have done this type of engagement activity really worth the time collecting and are they being used for decision making because they are things you can immediately measure?

Led by:
Bennett Levitan, MD, PhD
Senior Director, Benefit-Risk Assessment, Epidemiology, **Janssen R&D** with
Jessica Scott, MD, JD
Head of R&D Patient Engagement, **Takeda**

5:45 - 6:00 pm

Mapping Quality of Life Metrics To Trial Protocols: What BioPharma Can Learn from LUNGevity's Metrics Initiative

The question of "What is important to patients and how is industry assessing this into clinical developments?" is one that is continuously asked. So what is being done in the field to help address this challenge? In this session, LUNGevity will share how they are mapping patient quality of life metrics to a protocol which also takes a deeper look at operational aspects such as how many study visits are required and the commute/wait time between appointments and evaluating what the true patient burden is that each of the aspects of the protocol adds. From that, you can create an outcome that you can work on improving and measure your interventions not just on the standard of ROI but on the performance in reducing that burden to patients. Implementation process and lessons learned will be shared that can be adapted to additional patient engagement stakeholders.

Upal Basu Roy, PhD, MPH
Vice President, Research, **LUNGevity**

TRACK B: VIRTUAL TRIALS & SITE / CRO COLLABORATIONS

3:45 - 4:30 pm

Direct-to-Patient Clinical Trials Next Milestones and Actions to Get There Panel

We have called direct-to-patient trials, virtual trials, flexible trials, siteless trials, remote trials, decentralized trials and more. Many of us have done pieces of these types of trials, but as an industry, this is still not the norm by a long shot. In this discussion, we report on our progress, identify what's missing to close the gaps and next steps and call to action.

- How can we broaden our virtual approach so more patients will want to participate?
- How can partial virtual trial elements be more beneficial to patients than a full virtual trial?
- What are the existing challenges and how can we address these challenges?
- How are we addressing patient recruitment issues with virtual trials (ie: patients don't want people in their homes, etc)
- Patient perspectives on participating in virtual clinical trials

Led by: **Tammy Guld,** *Senior Director, Janssen Clinical Innovation,* **Janssen**
with
Wendi Lau, *VP, Operational Improvement & Reporting Excellence,* **Astellas Pharma**

4:30 - 5:15 pm

Best Practices for Partnering with Patients on the Direct-to-Patient Trials Model Panel

Having direct-to-patient trials and more telemedicine options is a way to reduce the burden to patients, however:

- How do we incorporate patient involvement in these remote manners?
- Is the approach different?
- How do you maintain that relationship with the patients?
- Patient feedback and maintaining communication

5:15 - 6:00 pm

Creating and Executing an Outstanding and Inclusive Patient Experience from the CRO and Site Perspectives Panel

- How do patients define an optimal experience and how can patients and pharma/CRO jointly support sites to get there?
- What are the biggest pain points for sites and how can sponsors help alleviate some of the challenges?
- How do sponsors and CRO's collaborate in site engagement, site assessment?
- What can we do to select sites that are optimizing the patient experience to improve recruitment and retention?
- Patient Perspectives on what has the greatest impact on their enrollment or retention at a trial site?

Led by: **Archana Sah,** *Chair, Oncology Board*, **Society for Clinical Research Sites (SCRS)**
with
John-Manuel Andriote, *Patient and Advocate*

Scott Gray, *CEO*, **Clincierge**

Erica Prowisor, *Global Head, Recruitment & Retention*, **IQVIA**

TRACK C: DIVERSITY & INCLUSION

3:45 - 4:45 pm

Current Efforts for Educating and Enrolling Diverse Populations in Clinical Trials Panel

This panel will discuss approaches to increase enrollment and broaden eligibility criteria (where clinically and scientifically appropriate) of underrepresented populations and to help include more diverse trial participants.

- What effective efforts are being done by sponsors to ensure more diverse populations are represented in trials? How are they addressing the issue that many diverse populations do not even have access to clinical studies?
- How can sponsors build bridges to the communities to gain their trust and demonstrate that they are a value partner?
- How can sponsors be more strategic in where they put trial sites in order to provide more opportunities for a representative population?
- How can sponsors expand on Community Ambassador Programs and the engagement of community partners to increase participation and awareness in diverse and historically underrepresented or underserved populations?
- What are scalable examples?

Moderated by:

Quita Beeler Highsmith, MBA
Head of Alliance and Advocacy Relations, **Genentech**

Panelists:

Luther T Clark, MD, FACC, FACP
Deputy Chief Patient Officer & Global Director, Scientific, Medical and Patient Perspective, Office of the Chief Patient Officer, **Merck**

Staci Hargraves
VP, Operations, Portfolio & Strategy, **Janssen R&D**

Jessica Riviere
Senior Director, Global Patient Advocacy, **Biogen**

Tina Aswani Omprakash
Patient and Advocate

4:45 - 5:30 pm

US Cancer Centers of Excellence Strategies for Increased Inclusion of Racial and Ethnic Minorities in Clinical Trials: Publication Findings and What Pharma Can Learn

This session will provide the findings from a study done with 8 US cancer centers who were able to recruit diverse patients with high & sustainable success in clinical trials and what pharma can learn to apply to their own diversity initiatives. Joining the discussion, Fox Chase Cancer Center/Jefferson, in conjunction with Merck and a patient representative will share the coordination and process that they use to deliver a 25% Diversity and Inclusion accrual rate in cancer.

Led by:

Jeanne Regnante
SVP, Community Education, **National Minority Quality Forum**
Center for Sustainable Health Care Quality and Equity

5:30 - 6:00 pm: Additional Topic TBD

6:00 pm

7th Annual Networking Reception
Graciously Hosted by: mrn MEDICAL RESEARCH NETWORK

DAY TWO - TUESDAY, MARCH 17, 2020

8:00 am

Morning Coffee & Tea

8:20 am

Co-Chair's Opening Remarks

Jamie Troil Goldfarb
Cancer Veteran & Advocate

Marilyn Metcalf, PhD
Senior Director, Patient Focused Development, Global Medical, **GSK**

Pablo Graiver
VP, Patient Engagement Digital Strategy Leader, Design & Delivery Innovation, **IQVIA**

INDUSTRY KEYNOTE

8:30 am

Amgen's Chief Medical Officer's Perspective on Patient-Centric Research & Building a Culture of Patient Centricity

Darryl Sleep, MD
Senior Vice President, Global Medical and Chief Medical Officer, **Amgen**

FDA GUIDANCE UPDATES & NEW AGENCY EFFORTS

FDA on the Latest Guidance Updates and New Agency Efforts on Patient Engagement

We are grateful to the FDA for choosing Patients as Partners US to provide four agencies within the FDA to present guidance updates and new patient engagement initiatives. Following the presentations, the FDA representatives will be available in a panel setting for open Q&A as it relates to patient engagement and regulatory decision making.

9:00 am

Center for Drug Evaluation and Research (CDER)

Meghana Chalasani
Operations Research Analyst, Office of Strategic Programs

9:10 am

Center for Biologics Evaluation and Research (CBER)

Karen Jackler
Patient Engagement Program Manager

9:20 am

Center for Devices and Radiological Health (CDRH)

Anindita Saha
Director of External Expertise and Partnerships (EEP)

Michelle Tarver, MD, PhD
Director of Patient Science & Engagement

9:30 am

Office of Pharmaceutical Quality (OPQ)

Michael Kopcha, PhD, RPh
Director

9:40 am

FDA Multi-Center Patient Engagement Q&A Panel

Meghana Chalasani
Operations Research Analyst, Office of Strategic Programs, **Center for Drug Evaluation and Research (CDER)**

Karen Jackler
Patient Engagement Program Manager, **Center for Biologics Evaluation and Research**

Anindita Saha
Director of External Expertise and Partnerships (EEP), **Center for Devices and Radiological Health (CDRH)**

Michelle Tarver, MD, PhD
Director of Patient Science & Engagement, **Center for Devices and Radiological Health (CDRH)**

10:05 am

Reducing the Burden to Patients: An Interactive Audience "Pop-up" Session

A small group of companies will share solutions to reduce the burden to patients who participate in clinical trials. They will have one minute to tell us about their service or technology. When finished, the audience is welcome to visit these companies at their respective tables.

Guest Companies:
Bionical
MRN
Salem Oaks

10:25 am

Patients as Partners Café & Networking Break

- Breakfast
- Meet the Exhibitors
- Ask the Patients
- Networking

11:10 am

How Industry Can Inform Patients on Being Their Partner: Be a Partner vs How to Become a Partner Panel

Research conducted with the BioPharma industry stresses patients need to "be a partner" but is *not* saying "How to become a partner" and are not giving patients the educational tools they need to do so. Patients have also stressed that there is a challenge trying to figure out how to go about seeking BioPharma to offer their input. This session will address:

- What is the biopharma industry doing to increase awareness and knowledge for patients to be their partners?
- How is industry educating patients on truly being a partner who engages in research and trial design?
- How do you maintain the relationship with patients to be long term partners?
- Patient perspectives on being a partner vs becoming a partner

Moderated by:

Pan Patel
Director, Clinical Trial Patient Advocacy, **BMS**

Panelists:

Christeen Moburg
Head of Patient Advocacy, **Sangamo Pharmaceuticals**

Cindy Chmielewski
Patient and Advocate

Monica St Claire
Product Lead, Insights, **Inspire**

Susan Stein
Director, Patient Advocacy, **Agios Pharmaceuticals**

B.J. Viau
Board Chair, **Huntington's Disease Youth Organization**

11:50 am

Engaging with Patients and Survivors in the Preclinical Phase of Drug Development

In this session, Dr Aime Franco, Thyroid Cancer Survivor and Assistant Professor of Pediatrics at The Children's Hospital of Philadelphia, shares how she is involving patients within the preclinical phase of drug development. According to Dr Franco, involving patients and including patient centric questions that determine what is important to patients (quality or quantity of life outcomes) much earlier in the research timeline can have a significant impact in the laboratory. By engaging with patients early, researchers can:

- Start to understand if their therapeutic interventions start to change the way the mouse behaves and help identify side effects in advance to the patient setting
- Try to align endpoints in the lab with clinical endpoints and think about how they would be measuring and assessing outcomes in the patient

Aime Franco, PhD
Thyroid Cancer Survivor / Director, Pediatric Thyroid Cancer Translational Research Laboratory, **Children's Hospital of Philadelphia (CHOP)**

12:10 pm

The View @PatientsasPartnersUS

We are delighted to introduce "The View at Patients as Partners", which provides an interactive format set up as an interview segment for presenting organizations and the audience.

Hosts:

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

Jessica Scott, MD, JD
Head of R&D Patient Engagement, **Takeda**

Jamie Troil Goldfarb
Cancer Veteran & Advocate

Taren Grom
Founding Partner/Editor, **PharmaVOICE**

Guest Companies:
GlobalCare Clinical Trials
Health Perspectives Group

12:55 pm

Lunch & Networking Break

CORNERSTONE PRESENTATION

1:45 pm

An Update on the Centers of Excellence Program and Integrating Data into Annual Strategy: A GO_2 Foundation Case Study

The GO_2 Foundation for Lung Cancer launched the Community Hospital Center of Excellence program in 2014 with the goal of bringing high quality, multi-disciplinary care to the community setting where over 80% of all cancer patients are treated. As part of the program, a data collection program was started to help understand the current baseline, pinpoint areas for improvement, and identify high performing centers. This Impact Report has been instrumental in not only measuring success year to year, but has served as the fulcrum for the annual Centers of Excellence Summit where best practices are shared and high level goals for the following year are established.

This presentation will dig deeper into the data collection, use of the data, outcomes to date and how GO_2 have expanded the use of data within other areas of the organization with the sole goal of improving outcomes for lung cancer patients.

Leah Fine
Senior Director, Excellence in Screening & Care, **GO_2 Foundation for Lung Cancer**

2:15 pm

How GSK's Patient Council F2F Is Disrupting The Way GSK Does Clinical Research Through Robust Patients Engagement Initiatives

Alexandra McGregor, PhD
Investigator & Patient Council Coordinator, **GSK**

NEW PATIENT ENGAGEMENT TOOLS

2:45 pm

The National Health Council's Fair-Market-Value (FMV) Toolkit for Compensating Patients

Appropriate policies for compensating patients, patient organizations, and family members for patient-engagement activities have been a hot topic for those involved in patient engagement in recent years. The National Health Council (NHC) addressed this by devising a patient engagement compensation toolkit that includes a fair-market-value (FMV) calculator to generate reimbursement rates for patients and patient advocates who participate in patient engagement activities. Companies and patient groups can adapt and further customize the calculator for their own needs. The toolkit includes building blocks, such as an engagement activities list and compensation and contracting principles, as well as patient-friendly contract templates.

In this session, Dr Eleanor Perfetto, Executive Vice President, Strategic Initiatives at the National Health Council will provide an overview on the development of the toolkit, a review of its contents and a demonstration of the calculator.

Eleanor Perfetto, PhD
Executive Vice President, Strategic Initiatives, **National Health Council**

3:05 pm

CTTI has New Tools to Put Patients at the Heart of Clinical Research: Find Out How You Can Benefit

Patients are more engaged in clinical trials than ever before—but there's still great opportunity to strengthen collaboration between industry and patients throughout the entire clinical trial's lifecycle.

In this session, the Clinical Trials Transformation Initiative (CTTI), a private-public partnership comprised of stakeholders across the clinical trials ecosystem, will share:

- Insights from recent forums and ongoing collaborations with the FDA that aim to increase patient participation in regulatory discussions about medical products
- Evidence-based recommendations on engaging patient groups throughout all stages of medical product development
- A framework that sponsors can use to assess the financial impact of patient engagement on key business drivers, such as cost, risk, revenue, and time
- Solutions and best practices for ensuring that sponsors, patient groups, and other stakeholders create relationships that are mutually beneficial

Zachary Hallinan
Senior Project Manager, **Clinical Trial Transformation Initiative (CTTI)**

PATIENT ADVOCACY INITIATIVES

3:25 pm

National Breast Cancer Coalition's Project LEAD on How to Educate and Support Patients to be Partners

Project LEAD, run by the National Breast Cancer Coalition, provides breast cancer patients/advocates with the education and training they need to understand complex medical and scientific information, the nuances of research methodology, and the unique role advocates play in influencing the research agenda so that they can engage with researchers and the scientific community to ensure the patient's perspective considered in their work.

In this session, Fran Visco, President of the National Breast Cancer Coalition (NBCC), will share the following:

- How Project LEAD is designed to give patients/caregivers the educational tools and scientific training they need in order to have a seat at the table and become active partners with biopharma
- How the Project LEAD model could be applied to other disease areas in order to give more patients the opportunity to collaborate with biopharma

Fran Visco
President, **National Breast Cancer Coalition (NBCC)**

3:50 pm

The Outcome of an Externally-Led Patient Focused Drug Development Meeting that Benefited Patients, Industry and FDA

The CMT and IN patient and advocacy community, together with biopharma, healthcare providers, government officials and payors met with the FDA to conduct an Externally-Led Patient Focus Drug Development Meeting (EL-PFDDM) that provided an in-depth report of patient voices and perspectives from those living with the disease to inform biopharma and the FDA on unmet needs. The patient experience data collected and reported will provide biopharma with information that will help with new drug/device developments that matter to patients, help biopharma understand what they should be measuring and how to address the CMT/IN populations. The EL-PFDDM will also help develop a benefit-risk framework that the FDA may utilize in their regulatory decision making.

Allison Moore
Founder & CEO, **Hereditary Neuropathy Foundation**

4:15 pm

Conference Concludes