7th Annual
Patients As Partners
August 19-21, 2020 • Virtual
Demonstrating How Patient Engagement and Involvement Gets Done
DAY ONE - WEDNESDAY, AUGUST 19, 2020

All times are listed in Eastern Standard Time

9:10 am
Opening Remarks & Welcome
Kate Woda, Director, Patients as Partners

PATIENT KEYNOTE
9:25 am
Clinical Trial Experiences as a CF Patient and Insights on Trial Disruptions from COVID-19
Cystic Fibrosis (CF) patient and healthcare entrepreneur, Ronnie Sharpe, joins Patients as Partners US for the first time to share his clinical trial experience pre-COVID-19 and throughout COVID-19. Ronnie will discuss alternative options that were put in place to minimize those disruptions and ensure that the life-saving drug he is receiving through the trial would continue.

Moderated by:
Jeanne Regnante, Chief Health Equity and Diversity Officer/CEO, LUNGevity Foundation/Patient3i
Ronnie Sharpe, Patient Advocate and Cofounder/CSO, Savvy Cooperative

INDUSTRY KEYNOTE
9:55 am
Industry Keynote: Pfizer’s Chief Patient Officer on Advancing Patient-Centric Programs & Putting Patients First in R&D
Pfizer’s Chief Patient Officer, Dr Dara Richardson-Heron joins Patients as Partners US to provide her insights on the following:
• New role as Chief Patient Officer and vision for Pfizer
• What patient centricity looks like in a post-COVID state
• What pharma needs to be thinking about and doing to meet the expectations of patients of the future

Dara Richardson-Heron, MD, Chief Patient Officer, Pfizer, Inc Hosted with:
Jamie Troil Goldfarb, Patient Advocate

10:15 am
Five Minute Break

CUSTOMER SERVICE GURU KEYNOTE
10:20 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
Hosted with:
Jamie Troil Goldfarb, Patient Advocate

INDUSTRY KEYNOTE
11:10 am
Fireside Chat: Amgen's Chief Medical Officer's Perspective on Patient-Centric Research & Building a Culture of Patient Centricity

Moderated by:
T.J. Sharpe, Patient Advocate
Guest Speaker:
Darryl Sleep, MD, SVP, Global Medical and Chief Medical Officer, Amgen

Choice Between 3 Breakout Sessions:

A: Partnering Strategies
11:35 am - 12:25 pm
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:
Cindy Chmielewski, Patient Advocate
Maria Hadjidemetriou, Patient Advocate
John Novack, Head, Patient Engagement, Inspire
Susan Stein, Director, Patient Advocacy, Agios Pharmaceuticals
Rob Weker, Patient Advocate

B: Inclusion Initiatives
11:35 am - 12:25 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, Chief Health Equity and Diversity Officer/CEO, LUNGevity Foundation/Patient3i
Panelists:
Lynne Alston, Patient Advocate
Evelyn González, Senior Director, Office of Community Outreach, Fox Chase Cancer Center
Michelle Vichnin, MD, Global Lead, Patient Advocacy and Strategic Alliances, Merck

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INDUSTRY KEYNOTE
1:30 pm
Leadership Perspective on 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.
Barry Greene
President, Alnylam Pharmaceuticals
Desiree Lyon
Global Director, American Porphyria Foundation
Hosted with:
Pablo Graiver
VP, Digital Strategy, IQVIA
1:55 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:
Sarah Krüg, CEO, Cancer 101/ Founder, Health Collaboratory
Jessica Scott, MD, JD, Head, R&D Patient Engagement, Takeda
Jamie Troll Goldfarb, Patient Advocate
Guest Companies:

12:25 pm
Reducing the Burden to Patients: 4 Minute Quick Fires
Moderated by a pharma representative, the quick fire presentations provide a fast moving overview where a select group of companies demonstrate what’s possible in reducing the burden to patients who participate in clinical trials.
Led by:
Pan Patel, Director, Clinical Trial Patient Advocacy, BMS

Guest Companies:
Salem Oaks
Kevin Freiert
Principal & Founder
Clincierge
Pamela Guthrie
Director, Sales & Marketing
COUCH Health
Ash Rishi, CEO
Jiva Science
Ram Yeleswarapu, Advisor

12:50 pm
Lunch Break
Choice Between 3 Breakout Sessions on Applying Patient Engagement Initiatives and Demonstrating Impact

A: Applying Patient Engagement Initiatives & Demonstrating Impact: Alkermes
2:50 pm - 3:10 pm
Building a Patient Engagement Strategy in a New Therapeutic Area and How to Bring the Patient Voice to the Development Process

In this session, Maxwell Mulcahy, Associate Director, Patient Engagement for Alkermes walks the audience through how they are building an entirely new patient engagement and advocacy strategy into their new oncology sector. Key topic areas include:

- Aligning the patient engagement strategy with internal clinical development and medical affairs partners
- Building out a whole new set of patient and advocacy partners internally and externally to help really understand the patient experience as medicines are developed
- Collaborating with patients and advocacy on clinical trial design to better represent the experience and patient voice to help minimize patient/caregiver burden, minimize future amendments and help boost enrollment

Maxwell Mulcahy, Associate Director, Patient Engagement, Alkermes

Hosted with:
Marilyn Metcalf, PhD, Senior Director, Patient-Focused Development, Global Medical, GSK

B: Applying Patient Engagement Initiatives & Demonstrating Impact: Sanofi
2:50 pm - 3:10 pm
How Patients Changed the Course of Inclusion/Exclusion Criteria Across all Sanofi Oncology Clinical Trials That Require Biopsies

Patricia Roselle, Global Head, Patient Network Management, Sanofi

Hosted with:
Jamie Troil Goldfarb, Patient Advocate

C: Applying Patient Engagement Initiatives & Demonstrating Impact: Ultragenyx
2:50 pm - 3:10 pm
Ultragenyx’s Patient Journey & Education Initiative

In this session Ultragenyx, shares how & why they developed a rare patient journey, education website & the response from the rare patient community. Topics include how Ultragenyx:

- Developed a reference framework to empower patient & families with rare disease to advocate for themselves
- Helps patients & families find credible information and trusted resources to inform decision-making about life transitions and events
- Provides tools for making connections for support of their physical, mental, social and emotional needs
- Gains a better understanding of issues & concerns across the entire patient community that enables Ultragenyx to network & link to resources in other disease states

Kim Cohee, Director, Patient Advocacy, Ultragenyx
Lisa Schill, Vice President, RASopathies Network

Hosted with:
Pablo Graiver, VP, Digital Strategy, IQVIA
3:20 pm  Small Group Interactive Discussions
The concluding afternoon of day one will be dedicated to 30 minute small group discussion choices. These interactive discussions are first come first serve and have limited capacity. Registration is required in advance. Attendees may choose one discussion group to attend live over the course of the conference. All discussions will be available on demand.

To register for the topic of your choice, please email service@tcfllc.org with the Subject Line: Patients as Partners Small Group Discussion Choice.

Topic choices include:

3:20 pm – 3:50 pm  Bringing Patient Perspectives to the Value Proposition
- How best to assess patient perspectives
- Techniques for doing so
- Approaches to including in value assessments at all stages of the product life cycle
 Led by: Barry Liden, VP, Patient Engagement, Edwards Lifesciences

3:20 pm – 3:50 pm  Promoting Clinical Trial Awareness to Physicians, Patients and Caregivers of Clinical Trials
- Update on current efforts
- Opportunities to collaborate
- Urgent needs
 Led by: Beth Zaharoff, Senior Director, Patient Engagement, Alkermes

3:20 pm – 3:50 pm  Lessons Learned From Patient Engagement Missteps
- What are some patient engagement missteps that you/your organization have experienced?
- How were you able to pivot and develop initiatives/processes that are beneficial to patients, caregivers, healthcare professionals, etc.?
 Led by: Sarah Krüg, CEO, Cancer 101

3:20 pm – 3:50 pm  Creating BioPharma Collaborations to Drive Diversity in Clinical Trials
- How can industry do better partnering with each other as a unified front to move the needle forward?
- Turning discussion into action
- What are real examples of how we are moving forward?
 Led by: Melissa Gonzales, PhD, Inclusion Principal- External Partnering, Chief Diversity Office, Genentech

3:30 pm
Partnering Meetings Begin. Refer to page 5 details.
DAY TWO - Thursday, August 20, 2020

All times are listed in Eastern Standard Time

9:45 am
Opening Remarks
Kate Woda, Director, Patients as Partners

PATIENT KEYNOTE
10:00 am
The Patient View: Biogen/Eisai Alzheimer’s Trial Participant Jeff Borghoff’s Insights into His Experience in this 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.

Moderated by:
Marilyn Metcalf, PhD, Sr Director, Patient-Focused Development, Global Medical, GSK

Guest Speaker:
Jeff Borghoff, Patient Advocate

FDA Guidance Updates & New Agency Efforts
10:30 am
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 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.

Robyn Bent, Patient-Focused Drug Development Program Director, Center for Drug Evaluation and Research (CDER)
Karen Jackler, Patient Engagement Program Manager, Center for Biologics Evaluation and Research (CBER)
Anindita Saha, Director External Expertise and Partnerships (EEP), Center for Devices and Radiological Health (CDRH)
Michelle Tarver, MD, PhD, Director Patient Science & Engagement, Center for Devices and Radiological Health (CDRH)

11:00 am
Five Minute Break

11:05 am
FDA Multi-Center Patient Engagement Townhall Q&A
Moderated by:
Anindita Saha, Director, External Expertise and Partnerships (EEP), Center for Devices and Radiological Health (CDRH)

Panelists:
Robyn Bent, Patient-Focused Drug Development Program Director, Center for Drug Evaluation and Research (CDER)
Karen Jackler, Patient Engagement Program Manager, Center for Biologics Evaluation and Research (CBER)
Anindita Saha, Director External Expertise and Partnerships (EEP), Center for Devices and Radiological Health (CDRH)
Michelle Tarver, MD, PhD, Director Patient Science & Engagement, Center for Devices and Radiological Health (CDRH)

Choice Between 2 Breakout Sessions on:
Applying Patient Engagement Tools

A: Patient Engagement Tools
11:40 am - 11:55 pm
Be the Partner Patient Portal: Building the Global Trial Community
• Connect: talk to trial participants and trial alumni
• Engage: share study info and study data with the patients
• Partner: get to know the person behind the subject ID

Thomas Klein, Founder & CEO, Be the Partner
Hosted with:
Marilyn Metcalf, PhD, Sr Director, Patient-Focused Development, Global Medical, GSK

11:55 pm - 12:15 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 of Strategic Initiatives, National Health Council
Hosted with:
Marilyn Metcalf, PhD, Sr Director, Patient-Focused Development, Global Medical, GSK

B: Patient Engagement Tools
11:40 am - 11:55 pm
Roadblocks in a Patient’s Clinical Trial Journey and How Better Data Can Remove Them
A patient’s clinical trial journey is tricky to navigate. They match to too many trials, struggle with eligibility, and never hear back. It’s a traffic jam: Trial sites are flooded with unqualified leads; sponsors must delay trials. Discover how advocates, sponsors, and recruitment partners can, with the right data, collaborate to help patients in their journey.

Mike Wenger, VP, Patient Engagement, TrialScope
Hosted with:
Jamie Troil Goldfarb, Patient Advocate
B: Patient Engagement Tools
11:55 pm - 12:15 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

Pamela Tenaerts, MD, MBA, Executive Director, Clinical Trial Transformation Initiative (CTTI)
Hosted with:
Jamie Troil Goldfarb, Patient Advocate

12:15 pm
Lunch Break

ANNUAL KEYNOTE ADDRESS

12:50 pm
New Data on Patient Preferences and Experiences to Inform Patient Engagement Strategies and Tactics
Ken Getz, MBA, Director and Associate Professor, Tufts CSDD and Founder and Board Chair, CISCRP
Hosted with:
Pablo Graiver, VP, Digital Strategy, IQVIA

Choice Between 3 Breakout Sessions: Capabilities and Platforms for Trial Recruitment/Matching Patient Feedback & Access to Clinical Research

B: Clinical Trial Recruitment & Matching Strategies
1:15 pm - 1:30 pm
A New Platform to Track Patient Recruitment Effectiveness and Connect Patients into Clinical Trials Leveraging an “Open Table” Model
This panel will share how a consortium of pharma/biotech companies, advocacy groups and institutions are using a transformational Patient Recruitment Tracking Platform to connect and track patients to clinical trials, leveraging the leading online destination for patients seeking clinical trials. This “OpenTable” model provides patients an easier approach to find and be connected to a clinical trial. At the same time, transparency and reports of patient recruitment tactic performance and ROI across all vendors enables biopharma, advocacy groups and institutions to manage their efforts in recruiting patients into clinical trials more efficiently.
Moderated by:
Lisa La Luna, SVP, Patient Advocacy, S & Senior Advisor, WCG
Panelists:
Maha Dutt, Associate Director, Research Operations, Office of Clinical Research, University of Pennsylvania
Deborah Howe, Director, Patient Recruitment, BMS
Brendan O’Neill, Senior Director, Patient Recruitment Programs Clinical Development & Operations, Global Product Development, Pfizer
Bernadette Siddiqi, Associate Director, Research Partnerships, The Michael J Fox Foundation

C: Accessing Clinical Research
1:15 pm - 1:30 pm
Improving Access to Clinical Research in a Changing World
- The importance of working with patients to improve access to clinical research against a backdrop of the global COVID-19 pandemic and major societal change
- Overview of feedback from the Patient Advisory Council on areas to address that will positively impact change
- Discussion on how decentralized clinical trials also enable access to patients otherwise unable to join research by providing practical solutions to many common study challenges
Rosamund Round, VP, Patient Innovation Center, Parexel
Hosted with:
Jamie Troil Goldfarb, Patient Advocate

A: Leveraging Patient Feedback Strategies
1:15 pm - 1:30 pm
Beyond Insight Collection: Building Capabilities and Mechanisms to Share and Leverage Patient Feedback Throughout the Organization
- Identify research gaps to make more effective use of time and global resources to avoid repetition of patient initiatives.
- Leverage opportunities to share patient insights work across the organization
Abbe Steel, MSc, CEO, HealthiVibe
Hosted with:
Marilyn Metcalf, PhD, Sr Director, Patient-Focused Development, Global Medical, GSK

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AGENDA

Choice Between 2 Breakout Sessions: Patient Data Ownership & Direct-to-Patient Trials

A: Patient Data Ownership
1:30 pm - 2:30 pm
Progress on Patient Data Ownership and Access Initiatives and Next Steps
This multi-stakeholder panel will focus on the following:
- Progress of returning data to patients
- Where organizations are today with this initiative
- How to get other organizations on the bandwagon
- How patients can benefit from owning their data to drive their quality of care and direct care teams
- Next steps
The discussion will conclude with an update from Pfizer, Janssen, Takeda and BMS on the Patient Data Access Initiative (PDAI) that will provide an industry standard that is focused on retiring clinical trial data to patients.
Moderated by:
Vivian Cheng Larsen, MBA, Associate Director, R&D Patient Engagement, Takeda
Panelists:
Alexandra Berk, MA, Head, Real-World Evidence, Citizen
Jamie Troll Goldfarb, Patient Advocate
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

B: Direct-to-Patient Clinical Trials
1:30 pm - 2:30 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 possible, but as an industry, this is still not the norm by a long shot.
- How are we addressing patient recruitment issues with virtual trials (i.e.: patients don’t want people in their homes, etc)
- 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 (i.e.: patients don’t want people in their homes, etc)
- Patient perspectives on participating in virtual clinical trials
Moderated by:
Monique Adams, PhD, Director, Clinical Innovation Lead, Janssen
Mohammed Ali, Global Head Digital Trials, Global Clinical Operations, Boehringer Ingelheim
Panelists:
Jimmy Bechtel, Director, Innovation & Engagement, Society for Clinical Research Sites
Vera David, MD, Medical Director, Dermatology, Science 37
Wendi Lau, VP, Operational Improvement & Reporting Excellence, Astellas Pharma
Michael Poku, MD, MBA, Medical Director, Signify Health

Choice Between 3 Breakout Sessions: Applying Patient Engagement Initiatives and Demonstrating Impact

A: Applying Patient Engagement Initiatives & Demonstrating Impact: Sangamo Pharmaceuticals
2:30 pm - 2:50 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 Therapeutics 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 Therapeutics
Hosted with:
Marilyn Metcalf, PhD, Sr Director, Patient-Focused Development, Global Medical, GSK

B: Applying Patient Engagement Initiatives & Demonstrating Impact: Biogen
2:30 pm - 2:50 pm
How Biogen is Enhancing Diversity and Representation and the Impact on Clinical Research
In this session, Charity Roddy, Senior Manager, Patient Engagement, Biogen, shares with the audience how Biogen developed a patient engagement training program for their early drug discovery team.
Charity Roddy, Senior Manager, Patient Engagement, Biogen
Hosted with:
Pablo Graiver, VP, Digital Strategy, IQVIA

C: Applying Patient Engagement Initiatives & Demonstrating Impact: FDA
2:30 pm - 2:50 pm
Collaborative Communities: A New Approach to Impacting Public Health
In this session, Dr Michelle Tarver, Director of Patient Science & Engagement and leading the Collaborative Community effort at CDRH walks the audience through what a collaborative community is, what can we learn from it, and the impact it can have for all stakeholders by creating such a community.
Michelle Tarver, MD, PhD, Director Patient Science & Engagement, Center for Devices and Radiological Health (CDRH)
Hosted with:
Barry Liden, VP, Patient Engagement , Edwards Lifesciences

2:50 pm
Ten Minute Break
### 3:00 pm

**Small Group Interactive Discussions**
The concluding afternoon of day one will be dedicated to 30 minute small group discussion choices. These interactive discussions are first come first serve and have limited capacity. Registration is required in advance. Attendees may choose one discussion group to attend live over the course of the conference. All discussions will be available on demand.

To register for the topic of your choice, please email service@tcflc.org with the Subject Line: Patients as Partners Small Group Discussion Choice.

**Topic choices include:**

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<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Led by</th>
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<tbody>
<tr>
<td>3:00 pm – 3:30 pm</td>
<td>Implementing Clinical Trial Participant Surveys on a Global Scale</td>
<td>Abbe Steel, MSc, CEO, HealthiVibe</td>
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<td>• Discuss the operational and regulatory hurdles (and solutions) to planting clinical trial experience surveys</td>
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<td>• Allow participants to share lessons learned of what has worked/not worked</td>
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<td>• Focus on global implementation strategies</td>
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<td>• How best to assess patient perspectives</td>
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<td>• Techniques for doing so</td>
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<td>• Approaches to including in value assessments at all stages of the product life cycle</td>
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<td>3:00 pm – 3:30 pm</td>
<td>Measuring Return on Engagement</td>
<td>Sarah Krüg, CEO, Cancer 101/ Founder, Health Collaboratory</td>
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<td>• What tools are there to measure the impact of obtaining patient perspectives over time?</td>
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<td>• What are the hurdles and resistance?</td>
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<td>• How are you assessing return on engagement from a business perspective and from a patient perspective?</td>
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<td>3:00 pm – 3:30 pm</td>
<td>Can a Global Pandemic Improve Patient Access to Clinical Trials?</td>
<td>Lisa La Luna, SVP, Patient Advocacy, SME &amp; Senior Advisor, WCG</td>
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<td>• Private Sector/Academic/Government/Advocacy Consortium</td>
<td>Brendan O’Neill Senior Director, Patient Recruitment Programs Clinical Development &amp; Operations, Global Product DevelopmentAdvisor, Pfizer</td>
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<td>• Increasing patients options to multiple trial options (like OpenTable)</td>
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<td>• Centralized/Localized/Patient-Centric Trial Listings</td>
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<td>• Tracking patient recruitment tactics ROI across the industry</td>
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<td>• Building consumer awareness and minimizing disparities in clinical trials</td>
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<td>3:00 pm – 3:30 pm</td>
<td>Identifying Legal Barriers in Patient Involvement and Potential Pathways to Overcome Them</td>
<td>Candace Lerman, Patient, Advocate and Attorney Candace Lerman, Esq</td>
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<td>• Identify issues and compare notes on challenges or improvements with clinical trial experiences that require approval from legal and compliance. What did that look like? How did those conversations go? What was the outcome?</td>
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<td>• How can we break the disconnect from forward-facing pharma employees who interact with patients/caregivers/advocacy and legal/compliance? What tools can we come up with to help take action?</td>
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<td>• How to bring the patient voice to legal and compliance initiatives that impact patients? How can we inspire pharma to have those internal conversations?</td>
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<td>• How can the culture of Pharma shift to establish a more collaborative environment between clinical trials and legal/compliance departments?</td>
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<td>• What are the next steps? What patient engagement initiatives could legal/compliance be a part of to gain an understanding of the impact and urgency of their approvals?</td>
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<td>3:30 pm</td>
<td>Partnering Meetings Begin. Refer to page 5 details.</td>
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**AGENDA**

**PATIENTS AS PARTNERS**

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DAY THREE - Friday, August 21, 2020

All times are listed in Eastern Standard Time

9:45 am
Opening Remarks
Kate Woda, Director, Patients as Partners

INDUSTRY KEYNOTE

10:00 am
Fireside Chat: Johnson & Johnson’s Chief Medical Officer on Engaging with Patients as Partners

In this fireside chat, J&J’s CMO, Dr. Waldstreicher will share tangible examples from Johnson & Johnson on how the company keeps patients at the center of innovation and decision-making through:

• Creating an internal but independent patient-centered organization focused on patient safety.
• Engaging patients early, systematically and directly across important aspects of drug development and treatment.
• Collaborating with independent third-party organizations to share insights and best practices that are in patients’ best interests.
• Championing evidence- and science-based decision making informed by ethics and values.

Moderated by:
Sarah Krüg, CEO, Cancer101/ Founder, Health Collaboratory
Guest:
Joanne Waldstreicher, MD, Chief Medical Officer, Johnson & Johnson

CORNERSTONE PRESENTATION

10:30 am
An Update on the Centers of Excellence Program and Integrating Data into Annual Strategy: A GO2 Foundation Case Study

The GO2 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 GO2 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, GO2 Foundation for Lung Cancer
Hosted with:
Sarah Krüg, CEO, Cancer101/ Founder, Health Collaboratory

11:00 am
Ten Minute Break

11:10 am
Ask the Patient Panel: Clinical Trial Experiences, Treatment Pathway Decision Making and Designing an Ideal Trial

Patients and advocates take the lead in this panel discussion, where they share their clinical trial experiences, decisions regarding their treatment pathway and work with the audience on how they would design an ideal trial.

• What would it include and why?
• What would make a huge difference for patients?
• Giving and getting feedback preferences
• Who in the audience would be willing to implement something as a result of hearing these points?

Moderator:
Beth Zaharoff, Senior Director, Patient Engagement, Alkermes
Panelists:
Maria Hadjidemetriou, Patient Advocate
Steve Hamilton, Patient Advocate
Candace Lerman, Patient Advocate
Alfred Samuels, Patient Advocate

11:50 pm
Fireside Chat: How Investing in Patient Engagement Activities Brings Value Back to Patients

Led by:
Taren Grom, Founding Partner/Editor, PharmaVOICE
Guest Speaker:
Jessica Scott, MD, JD, Head, R&D Patient Engagement, Takeda

12:10 pm
Lunch Break
Choice Between 2 Breakout Sessions:
Diversity Initiatives & Measuring Patient Engagement

A: Clinical Trial Diversity
12:50 pm -1:45 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:
Luther T Clark, MD, FACC, FACP, Deputy Chief Patient Officer & Global Director, Scientific, Medical and Patient Perspective, Office of the Chief Patient Officer, Merck
Panelists:
Melissa Gonzales, PhD, Inclusion Principal- External Partnering, Chief Diversity Office, Genentech
Staci Hargraves, VP, Operations, Portfolio & Strategy, Janssen R&D
Lauren Johnson, Sr Manager, Patient Recruitment Solutions, ICON Plc
Tina Aswani Omprakash, Patient Advocate
Charity Roddy, Senior Manager, Patient Engagement, Biogen

B: Measuring Patient Engagement
12:50 pm -1:45 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?
Moderated by:
Bennett Levitan, MD, PhD, Senior Director, Benefit-Risk Assessment, Epidemiology, Janssen R&D
Panelists
Ken Getz, MBA, Director and Associate Professor, Tufts CSDD, Founder and Board Chair, CISCRP
Jessica Scott, MD, JD, Head, R&D Patient Engagement, Takeda
Karlin Schroeder, Senior Director, Community Engagement, Parkinson’s Foundation

Choice Between 3 Breakout Sessions on Advocacy and Academia & Patient Engagement Initiatives

A: Advocacy & Academia Patient Engagement Initiatives
1:45 pm - 2:10 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)
Hosted with:
Marilyn Metcalf, PhD, Sr Director, Patient- Focused Development, Global Medical, GSK

B: Advocacy & Academia Patient Engagement Initiatives
1:45 pm - 2:10 pm
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)
Hosted with:
Jamie Troil Goldfarb, Patient Advocate
C: Advocacy & Academia Patient Engagement Initiatives
1:45 pm - 2:10 pm
Mapping Patient Burden in Clinical Trial Participation:
Lessons from the COVID-19 Pandemic
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, 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 B. Roy, PhD, MPH, Vice President,
Research, LUNGevity
Hosted with:
Pablo Graiver, VP, Digital Strategy, IQVIA

Choice Between 2 Breakout Sessions:
Applying Patient Engagement Initiatives &
Demonstrating Impact

A: Applying Patient Engagement Initiatives &
Demonstrating Impact: GSK
2:10 pm – 2:40 pm
Better Together: How GSK’s Oncology Patient Council
is Changing Their Research, Communication and
Understanding of Partnership
One year on, the Oncology Patient Council is sharing our
experiences in building collaborations, seeking and giving
advice, and navigating the inevitable challenges of working in
large organizations. Together we are celebrating the victories of
improved protocols, informed consents, educational materials,
and media platforms, as well as sharing some lessons learned
in how to create efficient, effective, and thoroughly enjoyable
engagements for patients, pharma, and the stakeholders who
will benefit from work that is making a difference.
Moderated by:
Alexandra McGregor, PhD, Investigator & Patient Council
Coordinator, GSK
Panelists:
Melissa Crouse, Patient Advocate
Jessie Daw, Patient Advocate
David Downs, Patient Advocate
Sarah Kaehny, Patient Advocate
T.J. Sharpe, Patient Advocate
Rob Weker, Patient Advocate

B: Applying Patient Engagement Initiatives &
Demonstrating Impact: Parkinson's Foundation
2:10 pm – 2:40 pm
A New Paradigm of Patient Engagement in Research:
International Collaborations Between Sponsors and
Patient Advocacy Organizations
Karlin Schroeder, Senior Director, Community Engagement,
Parkinson’s Foundation
Natasha Ratcliffe, PhD, Research Involvement Manager,
Parkinson’s UK
Hosted with:
Jamie Troll Goldfarb, Patient Advocate

2:40 pm
End Of Conference