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in Clinical Research

Celebrating 10 Years

March 20 - 22, 2023 | Omni Shoreham Hotel, Washington, DC

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DAY ONE - Monday, March 20, 2023

7:45 am

Registration, Tea / Coffee *(Regency Ballroom Foyer, Lower Level, West Promenade)*

8:15 am

Co-Chair's Welcome & Opening Remarks

Tina Aswani Omprakash
Patient Advocate and Co-founder, **South Asian IBD Alliance**

Clare Grace, PhD
Chief Patient Officer, **Parexel International Inc**

8:30 am

PATIENT ADVOCATE KEYNOTE

Mandy Gonzalez has starred on Broadway in the megahit *Hamilton* as Angelica Schuyler and originated the role of Nina Rosario in the Broadway musical, *In the Heights*. Mandy also starred as Elphaba in the Broadway production of *Wicked* and is an accomplished film and TV actor.

Mandy is also a breast cancer survivor, advocate and author where she recently published her Young Adult novel series, FEARLESS, with Simon and Schuster. In her quest to create positive change, Mandy is the proud founder of #FearlessSquad—a social media movement for inclusiveness and positivity. Mandy will share her cancer journey with the Patients as Partners audience and address her advocacy work for diversity, access and inclusivity. The session will conclude with a performance from her debut solo album, "Fearless."

Mandy Gonzalez
Hamilton, In The Heights and Wicked Broadway Star, Author and Patient Advocate

8:55 am

ZEITGEIST TALK

The Evolution of Partnering with Patients: Past, Present and Future

As Patients as Partners celebrates its 10th anniversary, Sarah Krüg, industry veteran and patient advocate, joins us to highlight the transformative shift to partner with patients over the past decade. This session will provide a bird's eye view of the advances we've made, as well as the roadblocks and challenges we've encountered along the way. In this interactive session, perspectives across healthcare will be shared, along with insights, opportunities and actions we can take to co-design the future of healthcare WITH patients and their families.

Sarah Krüg
CEO/Founder, **Cancer101/ Health Collaboratory**

9:20 am INDUSTRY KEYNOTE

How Takeda Built in Patient Engagement throughout the R&D Process to Reduce Patient Burden

In this Fireside Chat, Dr Kristina Allikmets takes the audience through how Takeda embedded patient engagement within research and development, with examples specifically in the rare disease space, to ensure that the innovative medicines they develop could make a meaningful difference to patients' lives. Key topics include:

Kristina Allikmets, MD, PhD
SVP, Head of R&D, Plasma-Derived Therapies Business Unit
Takeda Pharmaceuticals

Moderated by:

Tina Aswani Omprakash
Patient Advocate and Co-founder
South Asian IBD Alliance

9:45 am
Grand Opening of The Patients as Partners Networking Cafe

(Regency Ballroom, Lower Level, West Promenade)

- Breakfast
- Exhibitor Foundation Walk
- Ask the Patients
- Networking
- "Charge-up" at the Patient as Partners Charging Stations- *hosted by* yprime

10:25 am
ASK THE PATIENTS

Patient Perspectives on How R&D Organizations can Better Operationalize Studies and Prepare Patients for Clinical Trials

Patients take the lead in this panel discussion. They will share their clinical trial experiences and challenges and address three key topics including: Community Engagement, DCTs, and Returning Data to Patients. Key topics include:

Community Engagement

- Before you participated in a trial, had you engaged in a conversation, training, or any other method about clinical research with your physician or health care professional?
- Have you had previous exposure to non-trial specific general education materials on clinical trials at your physician's office? Places that you visit daily (pharmacy, supermarket, CBO, FBO, work, etc.)?
- How can we better engage at the community level to build more awareness and trust with clinical research?

Digital Technologies and Flexible Trial Options

- Were elements of the trial remote? If yes, was this a reason as to why you decided to participate in the trial? How was that experience?
- If the trial had no remote components, would you have wanted the option to have trial visits at home and/or via phone/computer?
- What could be done better to reduce the burden to patients participating?

Returning Data to Patients

- Did patients have access to their data during or post trial?
- What data would patients have liked to receive?

Moderated by:

Ebony Scott
Senior Manager, Patient & Community Engagement Digital Optimization, **Walgreens Boots Alliance**

Panelists:

LaToya Bolds-Johnson
Patient Advocate

Katie Doble
Patient Advocate

Christopher Reed, JD
Patient Advocate

11:00 am

INTERACTIVE SESSION

Roundtable Session on Creating Ideas and Solutions with Patients on Community Engagement, Trust, DCTs and Data

This session is a follow-on from the previous session where attendees will work together in smaller groups to create ideas and form suggestions on the below topics. Patients will be available to help attendees as they brainstorm ideas. The topics include:

Community Engagement and Building Trust

- Gain patient input on where and how to engage at the community level and what we can do better to build trust amongst underrepresented populations

Digital Technologies and DCT/Hybrid Trials

- Patients provide their preferences on what they want and don't want with hybrid trials and input on the use of digital technologies in trials

Returning Data to Patients

- Patients share what data they want to receive and insights on how we can provide their individual data in a way they can actually do something with it

Moderated by:

Ebony Scott
Senior Manager, Patient & Community Engagement Digital Optimization, **Walgreens Boots Alliance**

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

11:55 am

Case Study: How Patient Advocacy is Truly Partnering with Pharma to Better Engage Communities and Design Inclusive Trials

TOUCH, The Black Breast Cancer Alliance shares case examples of how they have partnered with pharma on engaging with the Black breast cancer community to raise awareness, education around clinical trials and to design trials that include more opportunities to participate. Key topics:

- Collaborative efforts for designing trials that are diverse, inclusive and accessible
- Unique ways to engage with Black women in their communities to raise awareness, education and recruitment for clinical trials (ie: Hair and beauty shows, festivals, hip hop stations, etc)
- How to interface with the patients you are trying to reach in community to build trust (ie: how are you speaking to them? Do you look like them? How are you making a safe environment for them to trust you?)
- Impact of these collaborative approaches with advocacy and pharma

Ricki Fairley
Co-founder & CEO
TOUCH, The Black Breast Cancer Alliance

12:15 pm

Patient Burden-Reducing Solutions & Technologies Audience"Pop-Up" Session

A select group of companies will share solutions in one minute pop-up sessions that reduce the burden to patients in clinical trials. At the end of this quick fire session, the audience is welcome to visit these companies at their respective tables to learn more.

Led by:
Kai Bode
Director, Digital Innovation and Patient Strategy, Global Digital Analytics & Technologies Team, **Merck**

Brian Weiss *Founder and CEO* carebox	**Su Smith** *Director* ORIGINS Patient Focus	**Alex Baffa** *Manager, Marketing Content* greenphire	**Scott Gray** *Founder and CEO* Clincierge	**Tarra Shingler** *Chief Commercial Officer* STUDYKIK	**Del Smith, PhD** *Co-founder & CEO* ACCLINATE

12:35 pm - 1:35 pm

Luncheon, Networking and Optional Roundtable Discussions *(Regency Ballroom, Lower Level, West Promenade)*

- Lunch
- Exhibitor Foundation Walk
- Ask the Patients
- Networking
- "Charge-up" at the Patient as Partners Charging Stations- ***hosted by*** yprime

12:55 pm

Optional Luncheon Roundtable Discussions *(Regency Ballroom, Lower Level, West Promenade)*

Attendees have the option to join a choice of roundtables starting at 12:55 pm. Topic choices include:

Roundtable #1: How to Create Synergies between R&D and Commercial to Align on Patient-Centered Approaches and Research Objectives

This roundtable will provide lessons learned and best practices on creating synergies with R&D and commercial to align on patient-centered approaches. More specifically:

- How creating synergies with R&D and commercial and aligning on patient-centered approaches could help drive greater efficiencies
- Examples of partnerships between R&D and commercial and steps in creating that partnership
- Addressing challenges and next steps to overcome them

Led by:

Ebony Dashiell-Aje, PhD
Executive Director, Patient Centered Outcomes Science (PCOS)
BioMarin Pharmaceutical Inc

Roundtable #2: Post Trial Engagement: How Pharma Can Better Support Patients

In this roundtable, attendees will discuss ways to better engage with patients after their trial has completed. Specifically addressing:

- Is post-trial engagement happening within your organization and what does that look like?
- For those organizations who do not do post-trial engagement activities, why not and what can be done to change that?
- What does post-trial engagement mean for patients and how can pharma, biotech and sites do better job doing this?

Led by:

Sophia Cacciatore
Associate Director, Patient Advocacy
Ovid Therapeutics

Roundtable #3: Working through Legal Constraints Impeding Patient Engagement and Solutions to Overcome Them

This roundtable will address legal and compliance considerations for patient engagement and create ideas and solutions to address the following:

- Addressing the common legal and compliance challenges and creating solutions to help support advancing patient engagement
- How to partner with and build internal synergies with legal and compliance teams to collaboratively build solutions to work through barriers impeding patient engagement initiatives

Led by:

Christina Vitt
Director, Ethics & Compliance
Boehringer Ingelheim

1:35 pm - 2:25 pm

Two Track Choices of Case Studies: Applying Patient Engagement and Demonstrating Impact

TRACK A: Operationalizing Patient Engagement
(Hampton Room, East Promenade)

Track Chair:
Nisha Patel, MBA
Engagement Director, Global Demographics & Diversity, Global Clinical Delivery, Global Clinical Operations, R&D, **GSK**

TRACK B: Impact Measures
(Blue Room, East Promenade)

Track Chair:
Sophia Cacciatore
Associate Director, Patient Advocacy
Ovid Therapeutics

TRACK A:

1:40 pm – 2:00 pm:

Setting the Strategy for Operationalizing Patient Engagement

Establishing internal strategies and an evidence-driven model to systematically advance patient engagement practices, meaningful cross-sector collaboration, and patient-centric partnerships across the clinical development continuum. In this session, you will hear foundational considerations for organizational endorsement, step-wise approaches to building a robust and actionable strategic framework, and case examples that demonstrate the operationalization of core values and considerations for future directions in patient centric drug development.

Key topics include:

- Organizational-level approaches to raising awareness and strengthening capacity around the reciprocal value of gaining patient input across the clinical development continuum
- Applied methods to measuring patient engagement based on impact metrics
- The role of partnering with legal and compliance to advance patient engagement practices
- Embedding and operationalizing health equity as a core value
- Considerations for future directions in patient engagement, including interdisciplinary methods and the importance of an intersectional lens

Vanessa Boulanger
Director, Patient Engagement, **Boehringer Ingelheim**

2:05 pm – 2:25 pm:

How Alexion Rare Disease, AstraZeneca Redesigned their Patient Engagement Operating Model to Make Patient Centricity Concrete

Alexion Rare Disease, AstraZeneca redesigned their rare disease organization by creating a design model that includes patients early and throughout all of drug development. Patient Experience (PEX) includes STAR (Solutions to Accelerate Results for Patients) is a design model that includes design thinking, leadership buy- in, capability building, and durable relationship commitment that is mutually beneficial and makes patient centricity concrete and attainable. Key topics include:

- How they designed the operating model, processes and policies and implemented employee patient-centric behaviors to meaningfully deliver on patient partnerships and early engagement
- How they worked with patient advocacy organizations and patients on co-creating the model
- The impact it has had on the organization and patient communities

Wendy Erler
VP, Global Head, Patient Experience, **Alexion Rare Disease, AstraZeneca**

TRACK B:

1:40 pm – 2:00 pm:

Measuring the Value and Impact of Patient Informed Medicines Development Model

Sanofi has been intentionally incorporating patient data and the patient communities into all aspects of R&D decision making for more than a decade. As part of their evolution, and desire to optimize their patient-informed medicines development mode, they established a comprehensive metrics reporting platform that measures value generation across the R&D continuum. These standard metrics and KPIs have enabled Sanofi R&D to identify how patient engagement is adding value to pre-approval programs by maximizing health value through better understanding of patient preference and experience, incorporating patient relevant outcomes, optimizing clinical trials for easier participation, establishing patient preference in benefit-risk analysis, and evolving meaningful collaborations with patient stakeholders. In this session, Sanofi shares the process behind creating and implementing these metrics.

Victoria DiBiaso, MPH, BScN
Global Head, Patient Informed Development & Health Value Translation, **Sanofi R&D**

2:05 pm – 2:25 pm:

Quantifying Patient Engagement Capabilities To Develop a More Sustainable, Standardized Patient Engagement Process within R&D Organizations

What are the most and least commonly implemented patient engagement activities? Does a more robust patient engagement plan impact study performance and outcomes? CSL participated as a working group member of a recent Tufts CSDD-led team that measured patient engagement capabilities across the industry and highlighted how those can be applied to support strategic operations.

Topic includes:

- Quantifying the adoption and impact of patient engagement activities
- Spotlighting gaps in patient engagement efforts related to health equity
- Detailing how CSL measured their organization's patient engagement preparedness
- Sharing feedback from patients around prioritized study performance outcomes
- Applying learnings to create a more sustainable, standardized process for incorporating the patient voice into the drug development process

Ellyn Getz, MPH
Director, R&D Patient Partnerships, **CSL**

Madison Reider
Manager, R&D Patient Partnerships, **CSL**

2:25 pm

Afternoon Break & Networking *(Regency Ballroom, Lower Level, West Promenade)*

- Exhibitor Foundation Walk
- Ask the Patients
- Networking
- "Charge-up" at the Patient as Partners Charging Stations- ***hosted by*** yprime

3:10 pm - 4:20 pm

Solutions and Technologies that Support DE&I, Access, Decentralized Clinical Trials and Patient Services

This section of the conference allows attendees to learn from a wide array of companies who provide solutions and technologies that support DE&I, access, decentralized clinical trials/hybrid trials and patient services.

Session Chairs:

Keri Yale, MBA
Head, Patient Affairs and Engagement, **Boehringer Ingelheim**

Angela Radcliffe
R&ED IT Digital Performance Improvement Lead, **BMS**

3:10 pm – 3:20 pm

Patients' Perceptions of Clinical Trial Information Sources

Understanding how to reach and engage with diverse patient populations is essential to increasing their participation in clinical trials. But what's the best way to connect patients to the most relevant trial resources? In this presentation, you'll hear compelling insights about patients' perceptions of clinical trials, including their overall desire to learn more about research as a care option and their high level of trust in the point of care as a place to get clinical trial information.

- Survey data on patients' levels of awareness, familiarity and interest in clinical trials
- How patients prefer to receive information—and which sources they trust most—about research as a care option across various therapeutic areas
- How to leverage the point of care to best reach patients about clinical trial participation opportunities

Kelsey Shore
Research Manager, **Phreesia**

3:20 pm – 3:30 pm

A Vision for Bridging the Commercial to Clinical Gap: How Shared Knowledge on Patient Insights can Accelerate Trial and Commercial Adoption

- A review of opportunities for synergy in patient insights that span clinical and commercial
- Vision for creating a shared insights capability
- The role of digital solutions in generating breadth, depth and scale of shared insights

April Lewis
Head, Patient-Centered Innovation, **ZS**

with

Mariah Blevins
CX Digital Solutions Manager, **GSK**

3:30 pm – 3:40 pm

Bedside to Bench – How the Patient-lived Experience Must Inform the Clinical Research Process

- Why the current state of trials makes it difficult for patients to participate in research
- How an internal patient SME leverages insights to improve the drug development process
- The importance of patient/caregiver perspectives in a fully-integrated stakeholder approach to reducing trial burden

Stacy Hurt
Patient Advocacy Ambassador
Parexel International Inc

3:40 pm – 3:50 pm

From-Patient Centric to People-Centric: How a More Thoughtful, Human-centered Approach Can Increase Engagement and Accelerate Recruitment

- Discuss ways of truly understanding the whole patient, beyond just their clinical features
- Identify the differences in people with otherwise identical inclusion / exclusion criteria
- Apply these learnings from end-to-end, across the entire clinical trial journey

Sarah McKeown-Cannon
VP, Growth, **Langland**

with

Sue Manber
Chief Patient Officer, **Publicis Health**

3:50 pm – 4:00 pm

Towards a Systematic and Integrated Approach to Patient Partnering for Patient-Centric Clinical Trials

- Operationalizing guidelines for quality patient engagement in practice
- Integrating patient engagement and insights for study-wide application
- Optimizing multi-stakeholder value and impact of patient engagement in clinical trials

Kevin Marsh, PhD
VP, Global Head Research Science
PPD, part of Thermo Fisher Scientific

4:00 pm – 4:10 pm

Make DEI Part of the Plan: Strategies for the Successful Enrollment of Diverse and Inclusive Patient Populations

Any meaningful commitment to diversity, equity, and inclusion (DEI) must be considered in the planning stage — not tacked on as an afterthought. This session will discuss making DEI a priority at the beginning of a trial; barriers to recruiting racially, ethnically, and socio-economically diverse populations; and share strategies for overcoming those challenges to ensure your trial includes and reflects populations that will ultimately benefit from them.

Erica Mercado
Senior Account Supervisor, **BBK**

4:10 pm - 4:20 pm

When to Ask Patients: 10 Case Studies in 10 Minutes

Savvy Cooperative works with companies across the industry to help them ask patients in order to improve their products and services. In this session will be doing a rapid fire of case studies to help you get ideas and examples of how other companies are engaging patients. You'll learn:

- At which points in drug development and commercialization companies are getting patient input on specifics such as protocols, materials, and technology
- Various methodologies that can be deployed to gather insights from patients that go beyond surveys and focus groups and allow for interactive patient feedback

Jen Horonjeff, PhD
Founder & CEO, **Savvy Cooperative**

4:25pm

Community-based Organizations' Perspectives on How Trial Sponsors Can Improve Their Clinical Research Initiatives

Community-based organizations (CBO) across several diverse patient populations share the challenges they face when it comes to inclusivity and accessibility to clinical research. This session will focus on feedback on how to engage with their respective communities, and insights on how pharma, sites and other stakeholders can improve efforts to be more inclusive. More specifically:

- What are some of the challenges and/or exclusions diverse patient populations face with entry points into clinical trials?
- Suggestions to build relationships with at the community level
- How do patients want to be approached for these community engagements?
- What do we need to do from a general clinical trial awareness standpoint in getting the word out within these communities?

Led by:

Ash Rishi
Founder & Chair of the Board of Trustees
Demand Diversity

Panelists:

Tina Aswani Omprakash
Patient Advocate and Co-founder
South Asian IBD Alliance

Shauna Whisenton
Manager, Sickle Cell Disease Community Engagement, **ASH Research Collaborative**

Calvin Roberts, MD
President and CEO, **Lighthouse Guild**

Perla Nunes
Director, Community Health Outreach, Julius L Chambers Biomedical Biotechnology Research Institute
North Carolina Central University

Scout
Executive Director, **National LGBT Cancer Network**

Angie Fedele
Director of Operations, Clinical Programs, **Autism Speaks**

5:20 pm

Annual Networking Reception and Optional Fundraising Activity

(Regency Ballroom, Lower Level, West Promenade)

5:30 pm

Optional Fundraising Activity for the Greater Washington DC Ronald McDonald House for Families Fighting Cancer

Please join us to assemble a gift bag for pediatric patients and caregivers of the Ronald McDonald House. In addition to fun items for the children, local families are in need of toiletries, which we are proud to donate and welcome the help from our attendees to assemble the bags. Please meet us at the annual networking reception on Day One, March 20th at 5:30 pm in the exhibit area.

Ronald McDonald House Charities®
Greater Washington, DC
Keeping families close®

DAY TWO - Tuesday, March 21, 2023

7:45 am

Registration, Tea / Coffee *(Regency Ballroom Foyer, Lower Level, West Promenade)*

8:15 am

Day Two Co-Chair's Welcoming Remarks

Emma Andrews, PharmD
VP, Global Patient Advocacy, **Pfizer**

Karen Peterson
Founder and Chief Patient Advocate, **Karen's Club**

8:30 am

R&D LEADERSHIP KEYNOTE

Walking the Talk: How Astella's Has Built a Foundational Culture of Patient Centricity throughout the Company, Culture and Values

Astellas Pharma's Global Head of Patient Centricity walks the audience through the process behind how they have built a foundational culture of patient centricity. This session will focus on how Astellas instills conscious awareness of the patient into everything they do and integrates that awareness into everyday work practices, regardless of where you sit in the organization. Topics include:

- Engaging internal stakeholders and creating a mindset of patient centricity as part of everyday practices in order to hold functions accountable
- Working with human resources to integrate patient centricity at the time of hire through the duration of their career at Astellas
- Measuring the progress/impact of their patient centricity initiatives and turning meaningful action into real change

Anthony Yanni, MD
SVP and Global Head, Patient Centricity, **Astellas Pharma**

8:55 am

Mapping What and How to Measure Patient Engagement Outcomes that Demonstrate Value for the Business and Patients: A Novartis Approach

In this session, Novartis shares how they are implementing consistent and systematic patient engagement activities with impact across the medicine lifecycle, including the identification of health outcomes which demonstrate value. An example of a patient engagement initiative where they have mapped out the actionable insight, what to track and how to measure will be provided. Attendees will learn how patient engagement drives business and development decision-making alongside robust value for patients.

Marc Boutin, JD
Global Head, Patient Engagement, **Novartis**

9:20 am

Morning Patients as Partners Cafe & Networking Break

(Regency Ballroom, Lower Level, West Promenade)

- Breakfast
- Exhibitor Foundation Walk
- Ask the Patients
- Networking
- "Charge-up" at the Patient as Partners Charging Stations ***hosted by*** yprime

10:00 am

EXECUTIVE FIRESIDE CHAT

Amgen's Efforts in Precision Medicine and Better Understanding Disease in Underrepresented Populations

Amgen's Dr Rob Lenz shares how they are building a foundational understanding of disease and progression in traditionally underrepresented patient populations, beginning with cardiovascular disease by engaging with patients in early clinical research. By understanding the biology of disease and genetic underpinnings, more data can be collected to help better develop precision medicines for specific patients. Dr Lenz will share case examples of how Amgen has partnered with patients and communities on this initiative and the impact it has had thus so far.

Rob Lenz, MD, PhD
SVP, Global Development, **Amgen**

Moderated by:

Cindy Geoghegan
Patient Advocate

10:25 am

The Annual VIEW @PatientsasPartners

The VIEW @PatientsasPartners provides an interactive interview segment to challenge and address how we can truly reduce the burden to patients in clinical trials.

VIEW Hosts:

Rebecca Vermeulen, RPh
VP, Global Patient Networks, Product Development Medical Affairs, **Roche**

Sabina Kineen
Patient Advocate

Pooja Merchant, MD
Head, Patient Partnerships and Engagement Oncology Global Medical Affairs, **Bayer Pharmaceuticals**

Participating Companies:

Clare Grace, PhD *Chief Patient Officer* parexel	**Jean McCoy** *EVP, Partnerships* reverba CELEBRATING 20 YEARS	**Veronica "Ronnie" Todaro** *President and CEO* VOZ ADVISORS

11:25 am

Three Track Choices: Interactive Sessions on Inclusive Patient Engagement Strategies, Long-Term Patient Engagement Initiatives, Applying Design Thinking for Systemic Patient Engagement

Interactive Session #1: Addressing How to Overcome the Barriers to Patient Engagement to Ensure Diversity and Inclusion

(Hampton Room, East Promenade)

About the Session:

While patient engagement is increasingly becoming a standard part of the drug development process, many operational barriers continue to hinder the uptake of systematic and truly inclusive patient engagement practices. In this interactive session, attendees will work in groups to co-create solutions to address those barriers.

Attendee Benefits:

- Develop a shared understanding of what inclusive and systematic patient engagement looks like
- Insights from colleagues across the sector on common barriers and roadblocks in patient engagement, including gaps in knowledge, skills, support and resources
- Steps for industry to ensure all stakeholders have the knowledge, skills and resources to embed inclusive patient engagement across the drug development process

Session Leaders:

Natasha Ratcliffe
Director, Community Engagement and Partnerships, **COUCH Health**

Priya Vijaykumar
Account Director, **COUCH Health**

Interactive Session #2: Novels Ways to Engage with Patients Over the Long Term

(Governor's Room, East Promenade)

About the Session:

Engaging with patients and their care partners throughout the drug development life cycle empowers them to share their needs and preferences, insights on endpoints and burdens associated with trial participation.

Additionally, there are numerous post approval topics related to how patients understand their treatment options, make treatment decisions, and experience their healthcare that can be addressed when a biopharmaceutical company has established long-term relationships with patients.

In this interactive session, attendees will work in groups to co-create ideas on effective ways to engage with patients and care partners long term to inform decision-making across the product life cycle.

Attendee Benefits:

- Gain insights into sustaining long-term relationships with patients and care partners
- Develop research questions to engage patient and care partner advisors
- Brainstorm creative and effective ways to maintain long-term engagement

Session Leaders:

Lynn Stone
Director, Strategic Accounts, **CorEvitas, LLC**

Additional Interactive Session Participants Include:

Jill Abell, PhD**, Executive Director, Patient, Caregiver and Consumer Experience & Immunology Insights Lead, Patient Innovation and Engagement Team,* ***Merck

***Carlos Cabrera**, Patient Advocate*

Steve Levine, MD**, Psychiatrist & VP, Patient Access,* ***COMPASS Pathways

Lisa Shea,** Scientific Patient Engagement Research Lead,* ***Janssen Scientific Affairs

Interactive Session #3: Design Thinking: The Secret Sauce for How to Embed Patient Engagement Systematically in R&D Organizations *(Blue Room, East Promenade)*

About the Session:

This interactive session will apply Design Thinking principles and processes to embed patient engagement systematically throughout an organization in a way that uses collective intelligence to align and prioritize activities according to purpose, milestones and resources.

Attendees will work in small groups with former NFL players for a problem-solving exercise that uses design thinking principles and processes to explore the role patient champions can have in driving positive health changes across diverse communities. This approach will then be demonstrated through a case example where NFL alumni contributed to cardiovascular wellness as an illustration of the impact this approach can have on patient engagement initiatives.

Attendee Benefits:

- Insights into how and why Design Thinking principles and process provide the secret sauce for success in developing patient engagement strategic roadmaps before developing specific patient engagement activities
- Understand the benefit of a proactive roadmap that aligns and prioritizes to overall strategy to enable planning and budgeting
- Learn how to leverage cross-functional stakeholder insights to bring more medical products of value to those in need, faster, through better partnership with patients and the patient community

Session Leaders:

Jessica Scott, MD, JD
President, **Legacy Health Strategies**

Sandra Prucka, MS, LCGC
Sr Director, Patient Engagement Strategy and Operations, **Legacy Health Strategies**

Ifeyinwa (Ify) Osunkwo MD
Chief Patient Officer, Novo Nordisk Rare Disease, **Novo Nordisk**

Additional Interactive Session Participants Include:

Vivian Larsen, MBA, *Chief Operating Officer,* ***Legacy Health Strategies***

Lisa Nelson, *Project and Account Manager,* ***Legacy Health Strategies***

Six former NFL players

12:30 pm Lunch & Networking *(Regency Ballroom, Lower Level, West Promenade)*

- Lunch
- Exhibitor Foundation Walk
- Ask the Patients
- Networking
- "Charge-up" at the Patient as Partners Charging Stations ***hosted by*** yprime

1:15 pm

Panel: Engaging Internal Stakeholders to Embed Patient Engagement in a Meaningful Way that Drives Value for Business and Patients

This session will address how to engage internal stakeholders to instill patient engagement throughout all initiatives across the organization that can enable organizational capabilities, frameworks, business planning and lead to better outcomes for patients.

- What are the elements of creating an internal business case to support patient engagement so that you can obtain the resources, finances and headcount you need to operationalize it?
- How do you develop a team with a variety of different capabilities who can embed patient engagement consistently throughout all the different processes in an organization?
- What are some approaches to instill commitment-driven behaviors and actions internally and address the different motivations of how internal stakeholders operate to ensure patient engagement gets done?

Moderated by:

Ebony Dashiell-Aje, PhD
Executive Director, Patient Centered Outcomes Science, (PCOS), **BioMarin Pharmaceutical Inc**

Panelists:

Angela Bilkhu
Senior Global Patient Partnership Director, Hematology Product Development: Medical Affairs (PDMA), **Genentech**

Deborah Howe
Director, Global Patient Recruitment and Engagement, **Alexion Rare Disease, AstraZeneca**

Schiffon Wong
Executive Director, Global Evidence & Value Development, **EMD Serono**

Angela Wheeler
President, Insight USA and Patient Center of Excellence Lead, **Lumanity**

2:05 pm - 2:30 pm Afternoon Break & Networking *(Regency Ballroom, Lower Level, West Promenade)*

- Exhibitor Foundation Walk
- Networking
- Ask the Patients
- "Charge-up" at the Patient as Partners Charging Stations ***hosted by*** yprime

TRACK A: DCT's and Diversity
(Hampton Room, East Promenade)

Track Chair:

Jasmine Benger, *Director, Research Services,* **CISCRP**

2:40 pm – 3:00 pm

Lessons, Learnings and Approaches to Building Trust with the Pediatric Cancer Community to Advance Childhood Cancer Drug Development

Day One Bio presents how they have conducted qualitative and quantitative research among patient organizations to better understand the community's perceptions of industry, the types of pharma engagement that are most important to them, and how pharma could best engage as a committed member of the pediatric oncology community. Topics include:

- How Day One Bio approached pediatric oncology patient organizations, given their historical lack of trust in pharma
- Establishing trust and collaborative relationships with the pediatric oncology advocates to support pediatric cancer drug development
- Seeking and sharing advocate feedback on what types of pharma engagement activities are most important to the community
- Eye-opening learnings and impact of conducting the research on relationships in the community
- How the findings have guided Day One's activities, both internally and externally

Christa Kerkorian, *VP, Patient Advocacy,* **Day One Biopharmaceuticals**

TRACK B: Patient Experience Data and Mobile Technologies *(Blue Room, East Promenade)*

Track Chair:
Marilyn Metcalf, PhD, *Senior Director, Patient Engagement Vaccines Lead, Patient Focused Development, Global Medical,* **GSK**

2:40 pm – 3:00 pm

Using Patient Preferences to Help with the Regulatory Process in Designing Clinical Trials

This session will provide a framework on how to incorporate patient preference data into the design of clinical trials and at different stages of product development. Key topics include:

- Gathering patient preference data to help in the regulatory approval process, particularly in the clinical trial phase
- How to prioritize endpoints that matter most to patients and develop a statistical design plan that is reflective of patients' tolerance for uncertainty

Barry Liden, JD, *Director, Public Policy / Former Chair, Science of Patient Input Working Group,* **DUSC Schaeffer Center / Medical Device Innovation Consortium (MDIC)**

Michelle Tarver, MD, PhD, *Deputy Director, Office of Strategic Partnerships and Technology Innovation, Program Director, Patient Science, Digital Health Center of Excellence, Center for Devices and Radiological Health,* **FDA**

TRACK A	TRACK B
3:00 pm – 3:20 pm **Capturing Patient Experience Data to Inform Decentralized/Hybrid Trial Design** For the first time, every GSK trial now has the option for patients to provide their experience through a standardized post-study participant feedback questionnaire. GSK shares how this approach has been augmented to capture patient experience and preferences around mobile participation with DCTs and remote trial services and how that is being used to inform and improve trial design. Key discussion points include: • How the study participant feedback questionnaire can be quickly deployed to capture patients' feedback about their trial experience • How patient experience feedback can be quickly incorporated into existing processes and internal boards • Provide internal considerations on privacy supporting sites and what do to with the data once you have responses • How patient experience data is being used as a consistent tool to gate gathered data, validate patient preferences that were given in the beginning of the trial with actual trial experience data **Peter Schaeffer, MBA,** *Digital and Process Optimization Leader,* **GSK**	**3:00 pm – 3:20 pm** **Using Patient Insights to Support Diversity & Inclusion in Clinical Trials** In this session, Sanofi, will share several practical examples of work they do with patient experience data and patient insights to support the recruitment of participants from historically underrepresented racial/ethnic minority in clinical trials. Attendees will learn: • How Sanofi uses early patient insights to design clinical trials for inclusivity • The role of behavioral science in supporting diverse enrollment • How Sanofi tracks their efforts to enroll diverse patients **Beth Brooks**, *Head, Patient Insights and Behavioral Sciences,* **Sanofi**
3:20 pm – 3:40 pm **Incorporating a Holistic Approach to DEI and DCT in Rare Genetic Disease Clinical Trials** BioMarin shares various strategies that have been incorporated to promote clinical trial diversity, which includes utilizing a hybrid decentralized clinical trial adoption to support the participant experience. Examples of the importance of partnering with patient advocacy groups, partnering with investigative sites and our ongoing educational efforts to support the patient journey in clinical trials will be provided. **Mia Elliott,** *Executive Director, Global Clinical Development* **BioMarin**	**3:20 pm – 3:40 pm** **Digital Health Coaching Intervention to Advance the Patient Experience of Cancer Survivorship (COACH)** Gilead's Global Patient Engagement and Pack Health share a collaborative initiative which leverages technology and patient partnerships to gain a deeper understanding of cancer survivors' unique needs, experiences, and concerns following completion of primary therapy and develops a new understanding of how Digital Health Coaching may bridge the gap between clinical and community settings. Key topics include: • Overview of the randomized waitlist COACH study – a clinical trial designed for non-therapeutic settings • Leveraging mobile and digital technologies to improve the patient experience • How data from connected devices will be used to explore the feasibility and acceptability of Digital Health Coaching to improve health outcomes • Approach to using evidence-based initiatives to engage patients in their own care and improve their care experience **Trudy Buckingham,** *Executive Director, Head, Global Patient Engagement,* **Gilead** **Kelly Brassil, PhD, RN,** *Director, Medical Affairs and Research,* **Pack Health, A Quest Diagnostics Company** **Susan Bredthauer,** *Patient Advocate*

TRACK A:

3:40 pm – 4:20 pm

Panel: Advancing Patient Optionality: Operationalizing DCTs to Give Patients More Flexibility while Creating Efficient Study Designs

When it comes to DCTs, hybrid trials, there are still a lot of uncertainty on what elements to build and how to operationalize them to give more flexibility to patients while creating efficiencies for the studies. Topics to address include:

- What are considerations when planning DCT's?
- How are we staying flexible to make sure DCT's and Hybrid trials reach more patients?
- How are we including patient input in the planning for DCTs/Hybrid Trials?
- What are solutions to support patients remotely, especially where technology may not be accessible or the preference?
- What are the challenges you see as you work through data coming from various approaches?
- How do we create more equity in clinical trials and therefore more access for more patients?

Moderated by:

Keri Yale, MBA
Head, Patient Affairs and Engagement
Boehringer Ingelheim

Panelists:

Mia Elliott
Executive Director, Global Clinical Development, **BioMarin**

Chris Venezia
CEO, **ProofPilot**

Nisha Patel, MBA
Engagement Director, Global Demographics & Diversity, Global Clinical Delivery, Global Clinical Operations, R&D, **GSK**

Todd McGrath
COO, **Medical Research Network**

TRACK B:

3:40 pm – 4:20 pm

Panel: Democratization of Clinical Trial Data for Patients: Where are We and Next Steps for Patients to Obtain and Control their Data

This session is dedicated to helping patients get easier access to their data and more control over it. We've made some progress but have a long way to go. Topics addressed include, but not limited to:

- How can we provide patients their individual data if they want it, in a way they can actually do something with it and choose for themselves what that is?
- What does patient data mean to patients?
- Should tokenizing data occur and how do patients feel about it?
- How are trial sponsors helping patients understand how their data is being used?

Moderated by:

Melanie Croce-Galis, RN, MPH
Executive Director, US Patient Engagement, **Novartis**

Panelists:

Angela Bilkhu
Senior Global Patient Partnership Director, Hematology Product Development: Medical Affairs (PDMA)
Genentech

Cindy Geoghegan
Patient Advocate

David Leventhal, MBA
Enterprise Clinical Trial Data Sharing Lead, **Pfizer**

TRACK A:

4:20 pm – 5:00 pm

Panel: Addressing the Impact of DCTs on Sites: What Needs to Be Done to Reduce the Burden on Coordinators and Patients

With clinical trial sponsors incorporating more DCT options for patients to participate remotely, the influx of technologies are creating more complexities for sites. This panel will address the current challenges sites are experiencing and what they need in order to help reduce the burden on coordinators and patients. Key topics include:

- What information do sites need earlier in trial setup in order to prepare for traditional vs decentralized trial components?
- What support mechanisms do sites need to be in place to help reduce burden on coordinators and patients?
- How can sponsors streamline technology training to make the transition to DCT easier for sites? What do sponsors need from sites in order to make this happen?

Moderated by:

Jimmy Bechtel
VP, Site Engagement
Society for Clinical Research Sites

Panelists:

MarieElena Cordisco, NP-C, APRN
AVP, Clinical Trials, Research and Innovation
Nuvance Health

Casey Orvin
Chief Commercial Officer, **CenExel Clinical Research**

Meghan Dixon
Project Manager
Accellacare Site Network, part of ICON, plc

TRACK B:

4:20 pm – 5:00 pm

Solving for the Digital Divide: Building Trust and Usability with Technologies to Support Patient Participation in Clinical Trials

Implementing mobile and digital technologies in clinical trials can sometimes create barriers to participation amongst patients who struggle to access them, are digitally challenged and/or do not have the bandwidth to support the utilization. This session will address the digital divide and solutions to reduce barriers to accessing and using technologies in clinical research.

Moderated by:

Sarah Krüg
CEO/Founder, **Cancer101/Health Collaboratory**

Panelists:

Ricki Fairley
Co-founder & CEO
TOUCH, The Black Breast Cancer Alliance

Stephanie Christopher
Director, Patient Advocacy, Rare Disease Global Product Development, **Pfizer**

Peter Schaeffer, MBA
Digital and Process Optimization Leader, **GSK**

5:00 pm

Day Two Patients as Partners Networking and Cocktail Reception *(Blue Prefunction, East Promenade)*

DAY THREE- Wednesday, March 22, 2023

7:50 am

Morning Tea/Coffee *(Blue Prefunction, East Promenade)*

8:20 am

Day Three Co-Chair's Welcoming Remarks

Luther T Clark, MD, FACC, FACP
Executive Director, Patient Innovation and Engagement, Global Medical and Scientific Affairs, **Merck**

Sabina Kineen
Patient Advocate

8:30 am

WHITE HOUSE PRESENTATION

The White House Office of Science and Technology Policy's (OSTP) Priorities in Health and Life Science and How Technology Can Be a Tool for Patient Engagement

In this session, a representative from the White House OSTP will discuss the critical importance of science, technology, and innovation in driving improved health outcomes for all Americans. Topics that will be covered include: President Biden's Cancer Moonshot, the President's mental health strategy and research efforts to support it, OSTP efforts to improve emergency clinical trials response, and lessons learned about how technology can weave through all of those themes as a tool for patient engagement.

Jacqueline Ward, PhD
Assistant Director, **White House Office of Science and Technology Policy**

9:00 am

GUEST KEYNOTE

Rebuilding FNIH's Approach to Patient Engagement as a Core Part of the Organizational Framework

A maverick in fighting for patient-centric research and as the former Chief Patient Officer of Merck, Dr Julie Gerberding was named FNIH's CEO to rebuild their approach to amplify the patient's voice across all of the FNIH's programs to provide greater impact on both science and patient outcomes. The FNIH is known for their ability to bring multiple stakeholders together in public private partnerships aimed to accelerate science that will help patients. Dr Gerberding will share several examples of strong patient engagement initiatives. Patient groups are strongly encouraged to share what more the FNIH can do to truly put the patient at the center of their work.

Julie Gerberding, MD, MPH
CEO, **Foundation for the National Institutes of Health (FNIH)**

Moderated by:

Tania Kamphaus, PhD
Director, Patient Engagement, **Foundation for the National Institutes of Health (FNIH)**

9:25 am

Merck's 5-Point Diversity Plan to Ensure Studies are Inclusive to all Representative Patient Populations

We are joined by several Merck stakeholders who provide the audience with a step-by-step approach on how they have developed and operationalized their diversity plan required by the FDA to improve enrollment of participants from underrepresented racial and ethnic populations in clinical trials. They will each share steps they took to implement this initiative, key recommendations and how it can be adapted beyond race and ethnicity to additional underrepresented patient populations.

- **Point #1: Corporate Philosophy and Strategy:** How Merck created and defined a corporate philosophy and strategy around diversity, equity and inclusion
- **Point #2: Product Development Team:** How Merck is working at the second level on the product development team strategy of what is needed to increase the diversity and inclusion into studies such as prostate cancer/HIV, etc. and what that targeted strategy needs to be
- **Point #3: Clinical Trial Team:** How the clinical trial team, who already has the protocol and design, is really building a plan to incorporate DE&I
- **Point #4: Feasibility Group:** How the feasibility groups determine if they can push this out into countries to see if the comparators are the standard of care that's used? Can the protocol design be executed, is it simply enough to be done in community based hospitals, etc
- **Point #5: Site Infrastructure:** Merck shares how they are working toward building the infrastructure at the site? What is needed to train and build coordinators skill sets at the hospitals when they haven't done this? Along with how to bring in a field force monitor in the Black community.

Led by:

Adrelia Allen, PharmD
Director, Clinical Trial Patient Diversity, Global Clinical Trial Operations, **Merck**

with

Kelly Clark
Head of US Partnerships and Global Site Development, **Merck**

Korin Martin
Director, Clinical Research Operation, Project Management Operations, **Merck**

9:55 am

Morning Patients as Partners Cafe & Networking Break *(Blue Prefunction, East Promenade)*

- Breakfast
- Exhibitor Foundation Walk Winners Announced
- Ask the Patients
- Networking
- "Charge-up" at the Patient as Partners Charging Stations - ***hosted by*** yprime

10:35 am

FDA Guidance Updates and New Patient Engagement Initiatives

Six FDA agencies 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.

Robyn Bent, RN
Director, Patient-Focused Drug Development (PFDD) Program, **Center for Drug Evaluation and Research (CDER), FDA**

Jamie Brewer, MD
Clinical Team Lead, Division of Oncology 3, Office of Oncologic Diseases, **Center for Drug Evaluation and Research (CDER), FDA**

Kathryn Capanna
Deputy Division Director, Division of All Hazards Response, Science & Strategic Partnerships, Office of Strategic Partnerships Technology Innovation, **Center for Devices and Radiological Health (CDRH), FDA**

Bray Patrick-Lake
Senior Digital Health Specialist, **Center for Devices and Radiological Health (CDRH), FDA**

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

Andrea Furia-Helms
Director, Patients Affairs Staff, **Office of Clinical Policy and Programs (OCPP), FDA**

12:00 pm

Applying Health Literacy Principles to Enhance Clinical Research and Participation in Trials: Next Steps and Actions

It is critical that clinical research information be communicated in a health literate way that is accessible, understandable, inclusive and representative of the patient populations. This will give researchers the ability to have improved conversations around consent and enables patients to make more informed decisions on their health. However, there are still challenges lingering when it comes to health literacy. This panel will address:

- Health literacy best practices that can be integrated at different phases of clinical research
- Engaging communities to co-develop health literate and culturally sensitive communications that meet their needs
- Addressing health literacy communications in a digital world

Moderated by:

Behtash Bahador
Associate Director, Health Literacy, **CISCRP**

Panelists:

Mehnaz Bader
Research Associate, **Pfizer**

Ella Balasa
Patient Advocate

Catina O'Leary, PhD
President & CEO, **Health Literacy Media**

Jessica Valencia
Director, Innovation in Patient Engagement, **Novartis Institutes for BioMedical Research (NIBR)**

12:40 pm

Convergence of ESG and Patient Engagement: Holding Pharma Accountable for Involving Patients in Clinical Research

Incorporating patient engagement as a metric in ESG could be a very powerful tool or mechanism to clearly demonstrate the value a patient's first approach brings to an organization, positioning patient engagement as a top strategic priority and generating business value that translates into societal benefit. In this session, PFMD's Nicholas Brooke shares their collaborative work focused on incorporating patient engagement within ESGs, what companies need to do internally to get this started, beginning with materiality assessments and next steps.

Following the talk pharma shares how and why the industry should begin to incorporate patient engagement within the organization's ESG Initiatives.

Nicholas Brooke
Executive Director, **Patient Focused Medicines Development (PFMD)**

Rebecca Vermeulen
VP, Global Patient Networks, Product Development Medical Affairs, **Roche**

Marc Boutin, JD
Global Head, Patient Engagement, **Novartis**

1:20 pm

End of Conference