PATIENTS as PARTNERS in Clinical Research

Demonstrating HOW Patient Involvement Gets Done to Better Support Access, Decision-making and Accelerating Medicine Development

2024 Event Highlights

Inside this Issue

Topics and who covered them | Photographs from the event | The reviews are in
Marking 11 years of the Patients as Partners® in Clinical Research conference, leaders in pharma R&D, FDA, and patient advocacy demonstrate how involving patients can enhance greater diversity, inclusion, decision-making and ultimately achieve greater efficiencies in medicine development.

On Day One, the program opened with the patient voice. Advocate Irisaida Méndez not only spoke about how a clinical trial changed her life, but also illuminated the accompanying financial toxicities. Trailblazer Dr Roslyn Schneider, BioMarin, explored patient advocacy's evolution to generate insights into strategies and best practices for the future.

A diverse panel of patients/caregivers gave their takeaways for industry from navigating clinical trials, and provided insights to be applied for future progress. Attendees participated in an interactive session using the LEGO® SERIOUS PLAY® method to innovate around the patient experience in clinical trials, defining what successful engagement looks like, and how we can enhance collaborations in clinical trials.

Representatives from different community-based organizations gave industry sharp insights to enhance clinical research initiatives.

On Day Two, Dr Henry Wei, Regeneron, took the audience through Regeneron's journey of letting science drive the organization's patient-centric approach to drug development and operations.

Linda Moir, an expert who led customer service excellence at Virgin Atlantic and the 2012 London Olympics, pulled from those experiences and gave the attendees lessons on high-value, low-cost customer service.

Panel discussions focused on leveraging sustainability for patient engagement goals, and empowering clinical sites to streamline trials and enhance patient care. The Annual VIEW returned to challenge and address how we can truly reduce the burden to trial participants.

For Day Three, Tufts CSDD’s Ken Getz presented new findings from their research on using an algorithm quantifying patient and site burden in clinical trials, and how this algorithm can be applied to inform protocol planning and design.

Michael Zincone, Pfizer, introduced the organization’s Patient Advocacy Leadership Collective and showed how the resource provided connectivity, community resources, and tools for sustainable capacity building.

BMS presented a novel case study on their work operationalizing the collection of self-identified Sexual Orientation and Gender Identity Data, a transformative industry approach to get a more holistic sense of who patients are.

The conference concluded with five FDA officials representing different agencies presenting the latest guidance updates and their new patient engagement initiatives.

Speakers presented on: impact measures; early engagement; operationalizing patient engagement; patient experience data & returning data to patients; DCTs, digital & mobile technologies; DE&I and community engagement; supporting DE&I, flexible clinical trials and patient services.

There were panel discussions, interactive sessions and roundtable discussions on:
• optimizing advocacy-biopharma collaboration to transform medicine development’s pace
• reducing patient burden
• tackling implicit bias
• strategic planning for recruitment excellence
• leveraging social listening in rare and chronic diseases
• establishing a patient-centric culture in biotechs
• patient engagement insights in peer-reviewed publications
• synergizing patient engagement and DE&I functions
• nurturing sustainable community relationships.

We are pleased to share highlights from Patients as Partners in Clinical Research 2024. A big thank you to everyone who participated in this year’s event.

Sincerely,
The Patients as Partners in Clinical Research team

Danny McCarthy
Multimedia Editor

Kate Woda
Senior Director

Valerie Bowling
Executive Director

Bre Bugbee
Senior Conference and Multimedia Marketing Manager

Meredith Sands
Executive Director, Strategic Partnerships

Shelby Casabura
Strategic Partnerships Manager

Elizabeth Bard
Senior Strategic Partnership Manager

Adam Kolanko
Senior Strategic Partnership Manager
“From networking with passionate, committed attendees, to top-notch presentations, this conference has evolved beautifully to serve all attendee stakeholders from diverse sectors of research, healthcare and government.”

- Dr Roslyn Schneider, BioMarin
\[\text{Patients as Partners Photo Gallery}\]

\[\text{"I'm leaving Patients as Partners feeling energized to keep doing the important work we do to ensure our mission to treat patients is at the forefront of our minds."}\]
- Dr Amanda Beasley, Amgen

For more photos, [click here](#)
Patients as Partners Photo Gallery

For more photos, click here
Patients as Partners Speaking Faculty Shines

Co-Chairs
- Ricki Fairley, MBA, CEO, TOUCH, The Black Breast Cancer Alliance
- Ebony Dashiel-Aje, PhD, Executive Director, Patient Centered Outcomes Science (PCOS), BioMarin Pharmaceutical Inc
- Sabina Kineen, Patient Advocate
- Stacy Hurt, Chief Patient Officer, Parexel International Inc
- Barry Nelson, Patient Advocate
- Rebecca Vermeulen, RPh, Head, Global Patient Partnership, Product Development Medical Affairs, Genentech, A member of the Roche Group

Keynotes
- The Personal Impact of a Clinical Trial: Irisaida Méndez, Patient Advocate
- Decoding the Evolution of Patient Advocacy: Roslyn Schneider, MD, MSc, FACP, FCCP, VP, Head of Global Patient Affairs, BioMarin Pharmaceutical Inc
- Turning Service on its Head: Linda Moir, Former Head / Former Head of Events Services, Virgin Atlantic Customer Service / London Olympics

Clinical Operations Zeitgeist on Bridging Science & Patient-Centricity
- Henry Wei, MD, Head of Development Innovation, Regeneron Pharmaceuticals Inc

VIP Session on Amplifying and Applying Patient Voices in Protocol Design
- Kenneth Getz, MBA, Executive Director & Professor, Tufts Center for the Study of Drug Development

FDA Guidance Updates and New Patient Engagement Initiatives
- Robyn Bent, RN, Director, Patient-Focused Drug Development (PFDD) Program, Center for Drug Evaluation and Research (CDER), FDA
- Bray Patrick-Lake, MFS, Senior Digital Health Specialist, Center for Devices and Radiological Health (CDRH), FDA
- Kathryn Capanna, MBA, 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
- Karen Jackler, MPH, Patient Engagement Program Manager, Center for Biologics Evaluation and Research (CBER), FDA
- Wendy Slavit, MPH, CHES, Senior Health Scientist, Patient Affairs, Office of Clinical Policy and Programs (OCPP), Office of the Commissioner (OC), FDA

Zeitgeist on Capacity Building for Patient Advocacy Groups
- Michael Zincone, Sr Director, Patient Advocacy, Pfizer
Patients as Partners Speaking Faculty Shines

"Engaging and practical sessions. Passionate speakers. Good mix of patient advocates with diverse disease perspectives. Great EDIB (equality, diversity, inclusion, and belonging) sessions."

- Colleen Castro, AbbVie
Patients as Partners Speaking Faculty Shines

Roundtable Leaders

- **Regan Sherman**, Former Senior Director & Head, Patient Advocacy, Entrada Therapeutics
- **Tracy Artim, MSN, CRNP**, Director, Operational Design & Patient Engagement, Global Development Operations, Amgen
- **Racquel Racadio, MPH**, Global Director, External Medical Engagement, Global Medical Organization, Amgen
- **Kristin Parkhurst**, Associate Director, Global Trial Optimization – Diversity, Equity and Inclusion (DEI) | Development Operations & Portfolio Management, Regeneron Pharmaceuticals Inc
- **Amy McCormick**, Senior Manager, Global Trial Optimization – Patient Engagement & Diversity, Equity and Inclusion (DEI), Regeneron Pharmaceuticals Inc

Patient and Caregiver Perspectives on Navigating Clinical Trials

- **Emily Parks**, Patient Advocate and Founder, POP!
- **Yvonne McLean Florence, MDiv**, Patient Advocate and 2023 Elevate Ambassador, National Coalition for Cancer Survivorship
- **Patrick O Gee Sr, PhD, JLC**, Patient Advocate, Founder & Chief Executive Hope Dealer, iAdvocate, Inc
- **Mackenzie Abramson, MPH**, Patient Advocate and Sr. Manager, Research Program Communications, Global Genes

Reducing Patient Burden Pop-Ups

- **Tarra Shingler**, Chief Commercial Officer, StudyKIK
- **Korinne Jew, Sr. Director, Enterprise Clinical Research & Medical Science, Medtronic**
- **Rick Scorzetti**, EVP, Chief Commercial Officer, Jumo Health
- **Erica Smith, PhD**, SVP, Business Development and Marketing, Spencer Health Solutions, Inc
- **Devra Densmore, MPA**, Founder & Principal Consultant, Elevate Advocacy, LLC
- **Su Smith**, Head of Patient Strategy, Origins
- **Jeff Evitts**, SVP, Sales, AutoCruitment

Impact Measures

- **Heather Pin**, Head, Patient Centric Operational Effectiveness | Patient Informed Development & Health Value Translation, Sanofi
- **Beth Brooks**, Head, Patient Insights and Behavioral Sciences (PIBS), Sanofi
- **Barry Liden, JD**, Director, Public Policy, USC Schaeffer Center for Health Policy & Economics
- **Tracy Artim, MSN, CRNP**, Director, Operational Design & Patient Engagement, Global Development Operations, Amgen
- **Annie Gilbert**, Global Patient and Site Engagement Lead, Boehringer Ingelheim

“It is wonderful to see pharma interacting with patients and community and also sharing lessons learned with each other and competitors for a common goal. I learned so much and am energized/empowered by all the leaders/speakers and courageous advocates to lead and push for change within my organization.”

- Dr Maria Jison, AstraZeneca
Patients as Partners Speaking Faculty Shines

"Well-curated topics, presentations and conversations. Awesome speakers. Great flow and timing."

- Ricki Fairley, MBA, TOUCH, The Black Breast Cancer Alliance

Early Engagement & Operationalizing Patient Engagement

- **Angela Bilkhu**, Senior Global Patient Partnership Director, Hematology Product Development: Medical Affairs, Genentech
- **Swathi Ramesh**, Director, Patient Insights and Solutions, AstraZeneca
- **Angi Gillen, MS**, Senior Director, Head of Patient Experience, Global Development | Clinical Operations, Gilead Sciences
- **Maggie McGuire-Kuhl**, VP of Research Engagement, The Michael J Fox Foundation (MJFF)
- **Jarrod Longcor**, Chief Operating Officer, Cellectar Biosciences
- **Erica Mercado**, Director, Growth, Publicis Health

Solutions and Technologies Supporting DE&I, Flexible Clinical Trials and Patient Services

- **Victoria DiBiaso, MPH**, VP, Head of Patient Informed Development & Health Value Translation, Sanofi
- **Emily Idoni**, Group Account Director, Publicis Health
- **Xoli Belgrave**, Senior Director, Global Head of Patient Inclusion, Parexel International Inc
- **Stephanie Terrey**, Senior Director, Patient Experience, CorEvitas, a part of Thermo Fisher Scientific
- **Rachael MacQueen, MBA**, Sr. Manager, Patient Centricity, Patient & Site Experience (PASE), Moderna
- **Samir Shah**, Principle, Shah Pharma Consulting Services LLC
- **EB McLindon**, CEO, Helios Clinical
- **Mark Scullion**, CEO, Atlas Clinical Research
- **Carlos Orantes**, CEO, Alcanza Clinical
- **Jennifer Horonjeff, PhD**, Founder & CEO, Savvy Cooperative
- **Angela Wheeler**, President, Strategy & Insight USA, Lead, Patient Center of Excellence, Lumanity

Community-Based Organization Insights for Enhancing Clinical Research Initiatives

- **Sabina Kineen**, Patient Advocate
- **Gary Ho**, Patient Advocate and Co-founder, Gout Support Group of America
- **Rucha Shah**, Patient Advocate, and Assistant Clinical Research Project Manager, ECOG-ACRIN Cancer Research Group
- **Desiree A. H. Walker**, Board President, Young Survival Coalition
- **Stacey Langley**, Patient Advocate

Leveraging Sustainability to Empower Patient Engagement Goals in Medicine Development

- **Nicholas Brooke**, Executive Director, Patient-Focused Medicines Development (PFMD)
- **Rebecca Vermeulen, RPh**, Head, Global Patient Partnership, Product Development Medical Affairs, Genentech, A member of the Roche Group
- **Susan Gaffney**, EVP, Membership, Development and Events, National Health Council
- **Gunnar Esiason, MBA, MPH**, Head of Patient Engagement, RA Ventures
Patients as Partners Speaking Faculty Shines

Empowering Clinical Sites: Strategies for Streamlining Trials and Enhancing Patient Care

- Joanne Monaghan, RN, CCRC, Clinical Operations Manager, Boston Clinical Trials
- Jessica Scott, MD, JD, CEO, Legacy Health Strategies
- Mahasweta Dutt, MS, MRA, CCRC, Associate Director- Clinical Research Operations, Office of Clinical Research, Penn Medicine
- Jillian Agnew, RN, CCRC, Clinical Research Coordinator, St Johns Center for Clinical Research

The VIEW @ PatientsAsPartners Hosts

- Karen Peterson, Founder and Chief Patient Advocate, Karen’s Club
- Adrelia Allen, PharmD, Executive Director, Clinical Trial Patient Diversity, Global Clinical Trial Operations, Merck Research Laboratories
- Lani Hashimoto, Associate Director, Patient Engagement Management, Novartis

The VIEW @ PatientsAsPartners Guests

- Stacy Hurt, Chief Patient Officer, Parexel International Inc
- Michelle Ouellette, Director, Patient-Powered Medicine, Medical & Scientific Management, Syneos Health
- Shawn Trutna, Senior Patient Engagement Lead, Syneos Health
- Ebony Scott, MSEd, MHC, Senior Manager, Patient & Community Engagement Digital Optimization, RWE Clinical Trials, Walgreens Co

Patient Experience Data & Returning Data to Patients

- Amy Fesmire-Baus, MPH, Patient Engagement and Recruitment Lead, BMS
- Jimmy Bechtel, MBA, VP, Site Engagement, Society for Clinical Research Sites (SCRS)
- David P. Leventhal, MBA, Senior Director, Data Sharing & Disclosure Lead, Worldwide Medical Operations, Information & Transparency, Pfizer
- Hayley Chapman, Senior Program Director, Patient-Focused Medicines Development (PFMD)
- Robyn Bent, RN, Director, Patient-Focused Drug Development (PFDD) Program, Center for Drug Evaluation and Research (CDER), FDA
- Vanessa Boulanger, Director, Patient Engagement, Boehringer Ingelheim
- Maggie McGuire-Kuhl, VP of Research Engagement, The Michael J Fox Foundation (MJFF)
- Veronica “Ronnie” Todaro, President and CEO, VOZ Advisors
- Ebony Dashiell-Aje, PhD, Executive Director, Patient Centered Outcomes Science (PCOS), BioMarin Pharmaceutical Inc
- Stacie Hudgens, CEO & Principal Scientific Advisor, Clinical Outcomes Solutions
- Selena Daniels, PharmD, PhD, Deputy Division Director, Division of Clinical Outcome Assessment (DCOA), Center for Drug Evaluation and Research (CDER), FDA
- Emily Epstein, LMSW, Clinical Behavioral Health Specialist, Genetics and Personalized Cancer Prevention Program, Weill Cornell Medicine
Patients as Partners Speaking Faculty Shines

DCTs, Digital & Mobile Technologies
- Patrick Floody, MBA, Executive Director, Global Clinical Trials Services, Regeneron Pharmaceuticals Inc
- Jennifer Yip, Associate Director, Digital Trials & Patient Engagement, Novartis
- Christopher Dell, MBA, Senior Manager of Patient Solutions, Pfizer
- Wessam Sonbol, CEO, Delve Health
- Ria Westergaard, PharmD, Director of Product Strategy, Clinical Trial Solutions, Evernorth Health Services
- Annlouise Assaf, PhD, Senior Director, Global Medical Patient Impact Assessment, Pfizer
- Ylenia Paleari, PhD, Patient Engagement Lead, Chiesi Farmaceutici SpA
- Eva Topole, MD, Clinical Digital Health and Innovation Lead, Chiesi Farmaceutici SpA
- Brett South, MS, PhD, Digital Systems and Machine Learning Lead, WMS, GMPIA, Pfizer
- Ajit Jadhav, Director, Digital, Worldwide Research, Development and Medical, Pfizer

DE&I and Community Engagement
- Samantha Guild, JD, President, AIM, Melanoma
- Eucharia Borden, VP of Programs and Health Equity, Family Reach
- Desiree A. H. Walker, Board President, Young Survival Coalition
- Meghan Blair, MS, CIP, Associate Director, Regulatory Affairs, Clinical Research Unit, Abramson Cancer Center, University of Pennsylvania
- Racquel Racadio, MPH, Global Director, External Medical Engagement, Global Medical Organization, Amgen
- Rachael MacQueen, MBA, Sr. Manager, Patient Centricity, Patient & Site Experience (PASE), Moderna
- Angi Gillen, MS, Senior Director, Head of Patient Experience, Global Development | Clinical Operations, Gilead Sciences
- Susan Gilchrist, Associate Director, CoDesign, Eli Lilly and Company
- Laura Engerman, Principal, ZS
- Kristin Parkhurst, Associate Director, Global Trial Optimization – Diversity, Equity and Inclusion (DEI) | Development Operations & Portfolio Management, Regeneron Pharmaceuticals Inc

BMS Case Study on Self-Identified Sexual Orientation and Gender Identity
- Lorena Kuri, MSMHC, Head, Diversity Strategy for R&D, BMS
- Donna Sattler, Director, Head of Standards Operational Management, BMS
- Jessica Brescher, MPH, Senior Clinical Scientist, BMS

HTA Initiatives for Inclusion of Patient Perspectives in Medicine Reviews
- Catherine Koola Fischer, MPH, Director, Patient Engagement, Institute for Clinical and Economic Review (ICER)

Optimizing Patient Advocacy/Biopharma Collaborations to Transform Medicine Development
- Victoria DiBiaso, MPH, VP, Head of Patient Informed Development & Health Value Translation, Sanofi
- Trish Davidson, MPA, PALADIN Consortium Director, Tufts Center for the Study of Drug Development
- Eda Baykal-Caglar, PhD, Director, Clinical Research Patient Engagement, The Michael J Fox Foundation
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