DIA

Metrics in Patient-Centered Drug Development

October 18-19 | Hilton Washington DC/Rockville Hotel and Executive Meeting Center | Rockville, MD

PROGRAM COMMITTEE

Marc Boutin, JD
Chief Executive Officer
National Health Council

Ellen Coleman, MPH
Senior Vice President
MK&A

Kenneth Getz, MBA
Director of Sponsored Research Programs and Associate Professor
Center For the Study of Drug Development, Tufts University School of Medicine

Elizabeth Lincoln, MA
Global Director of Engagement
DIA

K. Kimberly McCleary
Managing Director
FasterCures, A Center for the Milken Institute

Roslyn Schneider, MD, MSc, FACP
Global Patient Affairs Lead
Pfizer, Inc

Suzanne Schrandt, JD
Director, Patient Engagement
Arthritis Foundation

Overview

The medical products industry is at a critical juncture, with an opportunity to define medical product development operational activities and measures that will encourage and support meaningful integration of the patient perspective in drug development. This conference will examine the core principles of measuring the ROE of patient engagement and demonstrate how current and emerging approaches are being applied by industry colleagues to measure engagement impact on outcomes of importance to patient, industry, regulatory, and payer stakeholders. Lessons learned will provide a valuable resource when addressing challenges and resolving problems in the design and implementation of patient-centric initiatives and ROE measures.

Highlights

- Keynote Addresses from Robert Califf, MD, Professor of Cardiology, School of Medicine, Duke University and Theresa Mullin, PhD, Director, Office of Strategic Programs, CDER, FDA
- Strong focus on patient engagement in the US, as well as effective approaches and lessons from other regions
- Forward look to what regulators will expect in terms of approaches to collecting and incorporating patient input in development programs and submissions
- An inside look at how leaders and innovators in patient-centered medical product development have changed the culture of their organizations to support patient-centeredness

Who Should Attend

Biopharmaceutical and Medical Device Professionals involved in:

- Patient Advocacy/Engagement/Experience/Access (Including Chief Patient Officers)
- Patient Communications
- Medical Affairs and Medical Communications (Including Chief Medical Officers)
- Health Outcomes
- Study Endpoint Development
- Clinical Trial Design and Optimization
- Clinical Research
- Clinical Operations
- Benefit-Risk Assessment
- Pharmacovigilance and Risk Management

Schedule At-A-Glance

DAY ONE | WEDNESDAY, OCTOBER 18		ROOM
7:00AM-5:30PM	Registration	Plaza Foyer
7:00-8:15AM	Continental Breakfast and Networking	Plaza I
8:15-8:30AM	**Welcome and Opening Remarks**	Plaza II & III
8:30-9:45AM	**Keynote Addresses**	Plaza II & III
9:45-10:45AM	**Session 1:** Meaningful Patient Engagement - From Conceptual to Actionable	Plaza II & III
10:45-11:15AM	Refreshment and Networking Break	Plaza Foyer
11:15AM-12:45PM	**Session 2:** Defining Return on Engagement – Measuring What Matters	Plaza II & III
12:45-2:00PM	Networking Luncheon	Plaza I
2:00-3:30PM	**Session 3:** Cultural Change – A Key to Advancing Patient Centricity in Drug Development	Plaza II & III
3:30-4:00PM	Refreshment and Networking Break	Plaza Foyer
4:00-5:30PM	**Session 4:** Quantifying the Impact of Patient Engagement	Plaza II & III
5:30-6:30PM	**Networking Reception**	Plaza I

DAY TWO | THURSDAY, OCTOBER 19		ROOM
7:00AM-3:30PM	Registration	Plaza Foyer
7:00-8:00AM	Continental Breakfast and Networking	Plaza I
8:00-8:30AM	**DIA Overview**	Plaza II & III
8:30-10:00AM	**Session 5:** Quantifying the Impact of Engagement: View Through the Patient Lens	Plaza II & III
10:00-10:30AM	Refreshment and Networking Break	Plaza Foyer
10:30AM-12:00PM	**Session 6:** Resources for Patient Engagement Metrics	Plaza II & III
12:00-1:00PM	Networking Luncheon	Plaza I
1:00-2:30PM	**Session 7:** Case Examples of the Impact of Engagement	Plaza II & III
2:30-3:30PM	**Session 8:** The Emerging Role of the Patient in an Evolving Health Ecosystem	Plaza II & III

Learning objectives

At the conclusion of this conference, participants should be able to:

- Describe the current policy landscape for patient engagement in the medical product development life cycle and its impact on the needs of industry stakeholders in implementing patient-centric practices in product development and life cycle management
- Assess areas of commonality and divergence among key needs of patient, regulatory, industry, and payer stakeholders in the medical product life cycle as a basis for strategizing measures of return on engagement
- Discuss how to apply current and emerging approaches to measurement of the impact of engagement/ROE
- Assimilate lessons learned on "what worked" for early adopters in order to anticipate potential challenges and optimize patient engagement impact and ROE

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**Participants must attend both days of the conference in order to be able to receive an ACPE statement of credit. No partial credit will be awarded.*

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DAY ONE | WEDNESDAY, OCTOBER 18

7:00AM-5:30PM — **Registration** (Plaza Foyer)

7:00-8:15AM — **Continental Breakfast and Networking** (Plaza I)

8:15-8:30AM — **Welcome and Opening Remarks** (Plaza II & III)

Sudip Parikh, PhD
Senior Vice President and Managing Director, Americas
DIA

8:30-9:45AM — **Keynote Addresses** (Plaza II & III)

Theresa Mullin, PhD
Director, Office of Strategic Programs
CDER, FDA

Robert Califf, MD
Professor of Cardiology, School of Medicine
Duke University

9:45-10:45AM — **Session 1** (Plaza II & III)

Meaningful Patient Engagement - From Conceptual to Actionable

Session Chair

Suzanne Schrandt, JD
Director, Patient Engagement
Arthritis Foundation

Level setting work of collaborative groups has created actionable frameworks for meaningful engagement of patients in the medical product life cycle. Building on these concepts, groups such as TransCelerate and DIA-Tufts CSDD have been working to define medical product development operational activities and measures to encourage and support patient centricity. Additionally, some early adopters are anticipating what the regulatory environment for patient-centric medical product development will be as they structure their organizations and practices to become more patient-centric.

Suzanne Schrandt, JD
Director, Patient Engagement
Arthritis Foundation

Marc Boutin, JD
Chief Executive Officer
National Health Council

Anjali Trasy, MBA
Global Head, Patient Engagement Strategy
Sanofi

10:45-11:15AM — **Refreshment and Networking Break** (Plaza Foyer)

11:15AM-12:45PM — **Session 2** (Plaza II & III)

Defining Return on Engagement – Measuring What Matters

Session Chair
Roslyn Schneider, MD, MSc, FACP
Global Patient Affairs Lead
Pfizer, Inc

Consideration of "what matters" to all stakeholders in the medical products life cycle may help align the intent of patient engagement, measures of impact of patient engagement on health decisions, health care, and health outcomes. This session will identify key items important to representative stakeholders that may be affected by greater and iterative patient engagement. Each stakeholder representative will outline what they are measuring today to allocate their investment of time and resources and what they may measure in the future. Measures that overlap or contrast will be highlighted to set the stage for an interactive discussion between you and the panel.

Alan Rosenberg, MD
President
Healthcare Consulting, Inc.

Karlin Schroeder, MA
Director, Community Engagement
Parkinson's Foundation

Roslyn Schneider, MD, MSc, FCCP
Global Patient Affairs Lead
Pfizer, Inc

Christine Pierre, RN
President
Society for Clinical Research Sites

Ron Wincek, EdS
Parkinson's Advocates in Research (PAIR)
Member
Interactive Advantage Corporation

Kathryn O'Callaghan
Associate Center Director for Science and Strategic Partnerships (Acting), CDRH
FDA

12:45-2:00PM — **Networking Luncheon** (Plaza I)

DAY ONE | WEDNESDAY, OCTOBER 18

2:00-3:30PM

Session 3 (Plaza II & III)
Cultural Change – A Key to Advancing Patient Centricity in Drug Development

Session Chair
K. Kimberly McCleary
Managing Director
FasterCures, A Center of the Milken Institute

This session focuses on the role of organizational change in supporting patient-centric practices throughout the medical product life cycle. An expert panel will share experiences in fostering culture change using a combination of strategies. Measuring patient centricity as a means to shift both culture and practice will be explored.

Kathryn O'Callaghan
Associate Center Director for Science and Strategic Partnerships (Acting), CDRH
FDA

Nikki Levy
Vice President, Patient Engagement
Alkermes

Stephen Yates, PhD
Clinical Program Director and Head, Patient Engagement Strategy, Global Clinical Development and Medical Affairs Practice
UCB Biosciences, Inc.

3:30-4:00PM

Refreshment and Networking Break (Plaza Foyer)

4:00-5:30PM

Session 4 (Plaza II & III)
Quantifying the Impact of Patient Engagement

Session Chair
Kenneth Getz, MBA
Director of Sponsored Research Programs and Associate Professor, Center for the Study of Drug Development
Tufts University School of Medicine

There is growing consensus among stakeholders in the medical product life cycle that patient engagement is critical to assuring that patient needs - including those associated with clinical trial participation and with patient outcomes, are met. The moral, ethical, and pragmatic reasons for patient engagement are widely accepted, but research sponsors are also looking to understand the impact of patient engagement on study timelines and costs and on overall program success. Understanding return on investment, or return on engagement (ROE), is complicated by the availability of many different types of patient engagement efforts that could be employed and the lack of information about their value in a given context.

Stella Stergiopoulos, MS, MPH
Senior Project Manager, Research Fellow
Tufts Center for the Study of Drug Development

Linda Sullivan, MBA
Co-Founder and President
Metrics Champion Consortium, LLC

Kenneth Getz, MBA
Director of Sponsored Research Programs and Associate Professor, Center for the Study of Drug Development
Tufts University School of Medicine

5:30-6:30PM

Networking Reception (Plaza I)

DAY TWO | THURSDAY, OCTOBER 19

7:00AM-3:30PM — **Registration** (Plaza Foyer)

7:00-8:00AM — **Continental Breakfast and Networking** (Plaza I)

8:00-8:30AM — **DIA Overview** (Plaza Foyer)

Sudip Parikh, PhD
Senior Vice President and Managing Director, Americas
DIA

Mary Murray
Associate Director, Diversity and Patient Engagement
Bristol-Myers Squibb Company
Co-Chair, DIA Patient Engagement Community

8:30-10:00AM — **Session 5** (Plaza II & III)
Quantifying the Impact of Engagement: View Through the Patient Lens

Session Chair
Ellen Coleman, MPH
Senior Vice President
MK&A

Patients and patient organizations are invested in making sure new treatment innovations are available and offer value aligned with patient needs, and know their voice is integral to the process. As more resources, time, and energy are put forth by patient organizations to contribute to research and scientific discovery, how do they understand and measure return on their efforts? How have activities such as building registries, funding natural history studies, training research advocates, and assisting in trial recruitment and retention improve groups' abilities to meet their missions? How do, or could they measure benefits of such activities to the organization, patients, and ultimately the community which they serve?

Joanne Buzaglo, PhD
Senior Vice President, Research and Training Institute
Cancer Support Community

Andrea Ferris, MBA
President and Chairman of the Board
LUNGevity Foundation

Karlin Schroeder, MA
Associate Director, National Programs
Parkinson's Foundation

Ron Bartek
Founder and President
Friedreich's Ataxia Research Alliance (FARA)

10:00-10:30AM — **Refreshment and Networking Break** (Plaza Foyer)

10:30AM-12:00PM — **Session 6** (Plaza II & III)
Resources for Patient Engagement Metrics

Session Chair
Elizabeth Lincoln, MA
Global Director of Engagement
DIA

With increasing interest – and investment – in patient centricity, there are corresponding efforts to develop approaches for implementing patient-centric practice and tools for assessing the effectiveness and impact on drug development. Presenters in this session will introduce three tools and the work behind developing them. These tools help organizations navigate the development of their own patient-centric practices, help teams define, quantify, and evaluate the impact of their patient-centric efforts, and provide drug developers with quantifiable measures of various patient-centric activities on areas such as cost, speed, quality, and study participant impact.

Mary Jo Lamberti, PhD
Senior Research Fellow
Tufts Center for the Study of Drug Development

Rebecca Ashkenazy, MD
US Medical Affairs Lead, Women's and Men's Health
Pfizer, Inc

Elizabeth Lincoln, MA
Global Director of Engagement
DIA

12:00-1:00PM — **Networking Luncheon** (Plaza I)

DAY TWO | THURSDAY, OCTOBER 19

1:00-2:30PM

Session 7 (Plaza II & III)
Case Examples of the Impact of Engagement

Session Chair
Stella Stergiopoulos, MS, MPH
Senior Project Manager, Research Fellow
Tufts Center for the Study of Drug Development

The relationship of patient-centered initiatives to improvements in the drug development process and its outcomes can be difficult to pinpoint due to the complexity of the process and the many factors that also have an impact. Structured approaches to assessing the impact of these initiatives and broad dissemination of the results are key to validating the value of patient-centered practices in drug development. This session will explore case examples of patient-centered interventions that resulted in improved outcomes for stakeholders in the drug product life cycle. Presenters will share their experiences with implementing and evaluating a patient-centered initiative: What outcome objectives did they set? How did these influence plans for the patient-centered intervention? How was success defined and what measures were constructed? How did the implementation experience and results inform future work?

Mary Short, MSN, RN
Research Advisor, Clinical, MDU, Medical Pediatric Capabilities
Eli Lilly and Company

Debra Reinhard
Group Director, Clinical Sample Strategy and Operations
Bristol-Myers Squibb

Elizabeth Turcotte, MBA
Director of the Patient Hub
Bristol-Myers Squibb

Carrie Corboy, RPh, PharmD
Senior Director, Standards and Execution Excellence
Janssen Global Services

2:30-3:30PM

Session 8 (Plaza II & III)
The Emerging Role of the Patient in an Evolving Health Ecosystem

Session Chair
Marc Boutin, JD
Chief Executive Officer
National Health Council

Patients are demanding a more meaningful role in all aspects of our health ecosystem. In addition to a greater emphasis on patient involvement, emerging science, technology, value, and costs will disrupt health systems creating opportunities to re-envision how we promote, protect, and restore health and well-being. The downstream implications make patient-centered drug development a competitive necessity now and will intensify in the coming years.

Kelly Brantley
Vice President
Avalere Health

David Weinstock, MD
Associate Professor of Medicine
Dana-Farber Cancer Institute and
Harvard Medical School

Michael Goettler
Global President, Rare Disease
Pfizer, Inc

Lode Dewulf, MD, DPM, FFPM
Former Chief Patient Officer
UCB
Deputy Editor, TIRS and DIA
Global Forum

3:30PM

Conference Adjourned