Measuring Impact in Patient-Centered Drug Development Conference

October 2-3 | Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

PROGRAM COMMITTEE

Ellen Coleman, MPH, MS
President and CEO,
MK&A

Cynthia Grossman, PhD
Director, Science of Patient Input,
FasterCures, A Center of the Milken Institute

Patricia Jones, DrPH, MPH
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Program Director,
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Roslyn Schneider, MD, MSc, FACP
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Director, Patient Engagement,
Arthritis Foundation

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

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Overview

This conference is designed to help sponsor companies and patient organizations build their abilities to measure the effectiveness of patient-centric efforts. The focus will include developing and implementing measures, both quantitative and qualitative, to assess engagement effectiveness in reaching objectives for patient-centric practice. Also presented will be case examples of how peers have measured the impact of their patient engagement efforts at multiple stages throughout the medicines lifecycle, and uses of impact data within organizations to advance patient engagement programs and initiatives.

Highlights

- Short Course on building internal competency in patient engagement
- A hands-on, interactive working session on developing a new metric
- A deep look at how metrics are used in the healthcare industry to assess effectiveness of practices in health research
- An explanation of the Metrics Maturity Model and how it can improve patient-centric initiatives
- Patient Involvement throughout the conference, as it is designated as “Patients Included”

Target Audience

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
- Medical Science Liaisons
- Patient Support Services
- C-Suite Executives, Global Heads, Senior Directors, and Other Decision-Makers in:
- Patient Organizations
- Regulatory Agency Review

Schedule At-A-Glance

SHORT COURSE | MONDAY, OCTOBER 1		ROOM
8:00-9:00AM	Short Course Registration *Short Courses require a separate registration fee	White Oak A (Lower Level)
8:30AM-4:15PM	**Short Course:** Building Internal Competency in Patient Engagement	White Oak A

DAY ONE | TUESDAY, OCTOBER 2		ROOM
7:15AM-4:15PM	Registration	White Oak Foyer (Lower Level)
7:15-8:15AM	Networking Breakfast	White Oak B
8:15-8:30AM	**Welcome and Opening Remarks**	White Oak A
8:30-9:30AM	**Session 1:** Keynote Address	White Oak A
9:30-10:00AM	Refreshment and Networking Break	White Oak B
10:00-11:00AM	**Session 2:** Metrics Maturity Model	White Oak A
11:00AM-12:00PM	**Session 3:** Applying Metrics to Patient Engagement in the BioPharma/Devices Product Lifecycle	White Oak A
12:00-1:15PM	Networking Luncheon	White Oak B
1:15-2:45PM	**Session 4:** Where and When Should We be Measuring?	White Oak A
2:45-3:15PM	Refreshment and Networking Break	White Oak B
3:15-5:00PM	**Session 5:** What Measures/Metrics Are in Use?	White Oak A
5:00-6:00PM	Networking Reception	White Oak B

DAY TWO | WEDNESDAY, OCTOBER 3		ROOM
7:15AM-12:00PM	Registration	White Oak Foyer
7:15-8:15AM	Networking Breakfast	White Oak B
8:15-8:45AM	Patient Engagement Community Update	White Oak A
8:45-10:15AM	**Session 6:** Approaches to Developing, Demonstrating, and Disseminating Metrics	White Oak A
10:15 -10:45AM	Refreshment and Networking Break	White Oak B
10:45-12:15PM	**Session 7:** Hands on Interactive Session: Developing Metrics	White Oak A
12:15-1:30PM	Networking Luncheon	White Oak B
1:30-2:45PM	**Session 8:** Implementing Metrics - Where are We Going?	White Oak A
2:45-3:00PM	Closing Remarks	White Oak A
3:00PM	Conference Adjourns	

Learning Objectives

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

- Describe how to develop and use metrics to assess implementation, quality, and impact of patient engagement
- Identify objectives of patient, industry, and regulatory stakeholders for patient engagement and their influence on the selection of measures of engagement effectiveness
- Describe a framework for patient engagement metrics in the medical products lifecycle and how to assess the usefulness/fit for purpose of current and emerging approaches and measures
- Assimilate lessons learned by early adopters in order to anticipate potential challenges and optimize measurement of patient engagement impact

Continuing Education Credits

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 17 contact hours or 1.7 continuing education units (CEUs).

Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY NOVEMBER 15, 2018

Participants are able to receive an ACPE statement of credit for daily attendance. No partial daily credit will be awarded.

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by November 15, 2018, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.

DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 1.7 CEUs for this conference. Participants must complete the entire conference in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit for the day(s) that you attended the conference, you must sign in each day at the DIA registration desk upon arrival, complete the program evaluation and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning Monday, October 22, 2018.

To view DIA's Grievance Policy, visit DIAglobal.org/CE

Continuing Education Credit Allocation

Short Course: Building Internal Competency in Patient Engagement: Pharmacy 6.25 Contact Hours or .625 CEUs, UAN: 0286-0000-18-068-L04-P

Conference Day One: Pharmacy 6.25 Contact Hours or .625 CEUs, UAN: 0286-0000-18-069-L04-P

Conference Day Two: Pharmacy 4.5 Contact Hours or .45 CEUs, UAN: 0286-0000-18-070-L04-P

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SHORT COURSE | MONDAY, OCTOBER 1

8:00-9:00AM — **Short Course Registration**
*Short Courses require a separate registration fee

8:30AM-4:15PM — **Short Course:** Building Internal Competency in Patient Engagement

Session Chair
Ellen Coleman, MPH, MS, President and CEO, MK&A

This course precedes the conference on Measuring Impact in Patient-Centered Drug Development and will provide fundamentals about why and how to build such a function as a prelude to understanding how to measure the impact of patient engagement. This course is intended for those struggling to begin or build a patient engagement program and those in the early stage who have not yet considered that such program is necessary, but are curious to know more.

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

- Describe why integration of the patient perspective is integral for drug development programs
- Articulate examples of how companies have executed and benefitted from such programs
- Gain perspective from a patient point of view as to what constitutes meaningful engagement
- Frame high-level view of the steps a company needs to take to build a culture of patient engagement and what resources exist to help

Instructors
Nicholas Brooke, MBA, Executive Director, The Synergist

Sharon Dion, MBA, Vice President, MK&A

Kevin Kwok, Research Advocate, Parkinson's Foundation

Carol Meyer, R&D Patient Engagement Lead, Takeda Pharmaceuticals

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

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

Dawn Richards, PhD, Director of Patient and Public Engagement, Clinical Trials Ontario, Canada

DAY ONE | TUESDAY, OCTOBER 2

7:15AM-4:15PM — **Registration**

7:15-8:15AM — **Networking Breakfast**

8:15-8:30AM — **Welcome and Opening Remarks**

8:30-9:30AM — **Session 1:** Keynote Address: A Roadmap for Patient Engagement in Healthcare: Change Strategies and Measurements that Drive Them

Lee Thompson, MS, Senior Researcher, American Institutes for Research

The American Institutes for Research (AIR) "Roadmap for Patient and Family Engagement in Healthcare – Practice and Research," provides concrete guidance for achieving meaningful patient and family engagement in the healthcare field. This collaboration of AIR and the Gordon and Betty Moore Foundation was undertaken because, despite clear evidence that patient and family engagement helps achieve better quality of care, better outcomes, and lower healthcare costs, it had remained the exception, not the rule. Lee B. Thompson, MS, Senior Researcher at AIR, will share the vision for the Patient and Family Engagement Roadmap, the unique approach to its development, and how its strategies go beyond tactics to include the milestones that are key to assessing implementation progress and results.

9:30-10:00AM — **Refreshment and Networking Break**

10:00-11:00AM — **Session 2:** Metrics Maturity Model

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

Some organizations have robust metric programs and use metrics to support process improvement programs – others use a small number of metrics primarily for program oversight. In this session, what organizations measure and how they use the results will be described in the context of a five-stage metrics maturity model. The characteristics of each stage will be explored as well as the concept of basic, advanced, and exploratory metrics. Throughout the conference participants will use the framework to keep track of metrics described in conference sessions – determining whether they are examples of basic, advanced, or exploratory metrics and to which stage of the framework they align.

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

11:00AM-12:00PM — **Session 3:** Applying Metrics to Patient Engagement in the BioPharma/Devices Product Lifecycle

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

People and their organizations are held accountable for metrics relevant to their specific work in the development of medical products and allocation of resources is in part determined by those metrics. Patient engagement has potential benefit at discrete points and across the development lifecycle. Tools, models, and measures of quality and outcomes of those engagements are available and more are being developed. This session will outline how these may be applied to potentially improve both health and business outcomes.

Nicholas Brooke, MBA, Executive Director, The Synergist

Dawn Richards, PhD, Director of Patient and Public Engagement, Clinical Trials Ontario, Canada

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

12:00-1:15PM — **Networking Luncheon**

1:15-2:45PM — **Session 4:** Where and When Should We be Measuring?

Session Chair
Cynthia Grossman, PhD, Director, Science of Patient Input, FasterCures, A Center of the Milken Institute

Looking across the R&D lifecyle, there are several opportunities to measure the degree of patient-centric practices and possible impacts. Beyond identifying opportunities, we have yet to discuss issues such as how the point in the lifecycle might drive the types of patient-centered practices and how some activities may require different measurement approaches. This session will dive into opportunities to better match timing of measurement to demonstrate the impact of patient engagement across the full lifecycle.

Mathieu Boudes, PhD, PARADIGM Coordinator, European Patients' Forum, France

Bray Patrick-Lake MS, Director of Stakeholder Engagement, Duke Clinical Research Institute

James Valentine, Attorney, Hyman, Phelps & McNamara, PC

2:45-3:15PM — **Refreshment and Networking Break**

3:15-5:00PM — **Session 5:** What Measures/Metrics Are in Use?

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

This session will identify commonly used metrics and present case studies of specific applications. Difficult to measure areas will be examined with discussion of suitable metrics that can be developed to assess progress and impact of patient centered efforts.

Ellen Coleman, MPH, MS, President and CEO, MK&A

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

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

Heidi Ross, RN, BSN, Director of Clinical Trial Nursing Services, UBC

5:00-6:00PM — **Networking Reception**

DAY TWO | WEDNESDAY, OCTOBER 3

7:15AM-12:00PM — **Registration**

7:15-8:15AM — **Networking Breakfast**

8:15-8:45AM — **Patient Engagement Community Update**

Join us for an introduction to the DIA Patient Engagement Community (PEC). DIA's PEC is a learning Community for fostering collaboration between those who represent the patient and those who work to integrate patient needs into the process of medicines development, approval, and commercialization.

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

Tshaka Cunningham, PhD, Associate Director, Scientific Collaboration, DIA

8:45-10:15AM — **Session 6:** Approaches to Developing, Demonstrating, and Disseminating Metrics

Session Chair
Patricia Jones, DrPH, MPH, Lead, Common Metrics Initiative, Program Director, National Institutes of Health (NIH)

In this session, approaches or models for developing patient engagement metrics in varying phases of the clinical research process will be examined. Strategies and planning for dissemination of the metrics and sharing the results within and outside of organizations will be discussed.

Patricia Jones, DrPH, MPH, Lead, Common Metrics Initiative, Program Director, National Institutes of Health (NIH)

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

10:15 -10:45AM — **Refreshment and Networking Break**

10:45-12:15PM — **Session 7: Engage and Exchange**: Hands on Interactive Session on Developing Metrics

Session Chair
Cynthia Grossman, PhD, Director, Science of Patient Input, FasterCures, A Center of the Milken Institute

In this facilitated, small-group session, you will have the opportunity to design metrics for selected points in the medical product lifecycle. Focusing on intended use of the metric, groups will determine what type of metric will be most effective for the purpose and what to measure. You will design the measurement and its implementation process, including an approach to evaluating and disseminating results to key stakeholders.

12:15-1:30PM — **Networking Luncheon**

1:30-2:45PM	**Session 8:** Implementing Metrics - Where are We Going? **Session Chair** **Suzanne Schrandt, JD,** Director, Patient Engagement, Arthritis Foundation Measuring the impact of patient engagement efforts is a tool for ensuring meaningful exchange and for driving toward meaningful outcomes. This session presents a frank and forward looking discussion about addressing the constraints around utilizing patient engagement metrics and new initiatives that will help to advance the field. **Jennifer Miller, PhD,** Founder, Bioethics International and Good Pharma Scorecard, Assistant Professor, Yale University School of Medicine **Theresa Mullin, PhD,** Associate Director for Strategic Initiatives, CDER, FDA
2:45-3:00PM	**Closing Remarks**
3:00PM	**Conference Adjourns**

Measuring Impact in Patient-Centered Drug Development Conference

Exhibitor Directory

Evidera

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Evidera, PPD's peri- and post-approval business unit, is a leading provider of evidence-based solutions to demonstrate the real-world effectiveness, safety, and value of healthcare products. We help biopharma, biotech, and medical device companies generate the evidence needed to optimize the market access and commercial potential of their products.