Patient Engagement in Benefit-Risk Assessment throughout the Life Cycle of Medical Products

Tutorial: September 16 | Conference: September 17-18

Bethesda North Marriott Hotel and Conference Center Bethesda, MD

As of September 8, 2015

PROGRAM COMMITTEE:

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OVERVIEW:

Historically, patients have been targeted with education and promotion after product approval, but continuous engagement in benefit-risk assessment throughout the research and approval process is key to assuring that medical products will meet patient needs.

During this two-day conference, patient partners, academic and industry medical product researchers, and regulators will address the important challenge of how and when to best engage patients to more actively incorporate their voices into benefit-risk assessment throughout the life cycle of medical products. Multiple stakeholders will reach consensus on appropriate engagement of patient partners in benefit-risk assessment throughout the medical product life cycle; share effective approaches and assess methodological, operational, and regulatory challenges to implementation of effective patient engagement; and identify next steps for developing and adopting needed tools and practices that will result in better outcomes for patients.

FEATURED TOPICS:

- Key decision-making stages and patient engagement in the context of medical product development and benefit-risk assessment
- Setting the baseline for benefit-risk assessment and the current environmental context making patient perspective crucial to decision-making
- Regulatory, operational, and methodological challenges to patient engagement in a regulated environment
- Effective approaches to patient engagement in benefit-risk assessment throughout the product life cycle, including what can be learned from other aspects of clinical research and other types of health research
- Enabling patient partners to provide input on benefit and risk considerations
- Patient-initiated models for collecting patient perspectives

LEARNING OBJECTIVES:

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

- Discuss the importance, context, and approaches to appropriate engagement of stakeholders in benefit-risk assessments throughout the medical product life cycle
- Evaluate and propose solutions to regulatory, methodological, and operational challenges for all aspects of engagement in benefit-risk assessment
- Identify gaps in current knowledge in the practice of stakeholder collaboration in benefit-risk assessment and propose improvements that will result in better outcomes for patients
- Propose ways to increase engagement of other stakeholders in their own work within the medical product life cycle

This program has been partially supported by PCORI (the Patient Centered Outcomes Research Institute) through a Eugene Washington Engagement Award.

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- **Stated Preference Methods and the Science of Patient Engagement:** IACET: .3 CEUs

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IACET: 1.4 CEUs

Pharmacy:

- **Day 1:** 7.75 contact hours or .775 CEUs, 0286-0000-15-107-L04-P
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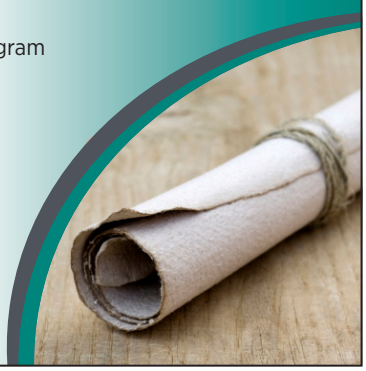

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WEDNESDAY, SEPTEMBER 16

12:30-1:30PM TUTORIAL REGISTRATION

1:30-5:00PM TUTORIAL

Stated Preference Methods and the Science of Patient Engagement

INSTRUCTOR

John F. P. Bridges, PhD
Associate Professor
Department of Health Policy & Management
Johns Hopkins Bloomberg School of Public Health

Invigorated by the FDA's patient-focused drug development (PFDD) and patient preference initiative for medical devices, there has been growing interest in the study of the preferences and priorities of patients and other stakeholders throughout the product life cycle. While preferences can be identified both qualitatively and quantitatively, emphasis has been placed on using scientifically valid ways of measuring preferences. Grounded in theories of choice from the disciplines of economics and psychology, stated-preference methods are a class of methods that can be used to identify what patients and stakeholders value most and what tradeoffs they are willing to make. This tutorial will provide participants with a basic overview of the variety of stated-preferences methods that can be used to measure the preferences of patients and other stakeholders in medicine. Utilizing lectures, case studies, and hands-on exercises to facilitate a practical understanding, stated-preference methods such as conjoint analysis, discrete-choice experiments, contingent valuation, and best-worst scaling will be explored as approaches to identify what patients and other stakeholders value.

WHO SHOULD ATTEND?

This tutorial is intended for researchers, patient advocates, and policy makers who have little to moderate knowledge about stated-preference methods and who aim to understand more about these methods and their possible applications. Some basic knowledge of survey methods, patient-reported outcomes, and statistical analysis (including linear regression) would be advantageous, but is not required.

LEARNING OBJECTIVES:

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

- Describe the variety of stated-preferences methods that can be used to measure patient preferences;
- Discuss the advantages of stated-preferences methods over alternative approaches to measuring values;
- Determine when a particular stated-preference method is appropriate for a particular research question and where to find appropriate guidance to apply the methods successfully

**Tutorial requires registration and is an additional fee.*

THURSDAY, SEPTEMBER 17

7:15-8:15AM **REGISTRATION AND CONTINENTAL BREAKFAST**

8:15AM **WELCOME & GOALS OF CONFERENCE**

Join the conversation and follow **#DIAEngage** for real-time updates.

Elizabeth Lincoln
Global Director of Engagement
DIA

8:30-10:00AM **SESSION 1: MEDICAL PRODUCT DEVELOPMENT, BENEFIT-RISK ASSESSMENT, AND PATIENT ENGAGEMENT: CONCEPTS AND CONTEXT**

SESSION CHAIRS

Patricia Furlong, BSN
Founding President and CEO
Parent Project Muscular Dystrophy

Marilyn A. Metcalf, PhD
Senior Director
Benefit-Risk Evaluation
GlaxoSmithKline

The purpose of this session is to discuss foundational concepts with all stakeholders together to establish the context of benefit-risk and patient engagement in medical product development and to agree to common terminology for the duration of the conference. The importance of benefit-risk assessment and key times it takes place in the product cycle, its meaning in the context of patient need, stakeholders to be involved, and the importance of patient partner engagement will be discussed. The foundations and meaning of many types of patient engagement will be an important focus of this session.

Environmental Context – Why is This Important Now?

Speaker Invited

Patient Perspective

Andrea Ferris
President and Chairman
LUNGevity Foundation

Overview of Medical Product Development and Benefit-Risk Assessment

Tarek Hammad, MD, PhD, MS, MSc, FISPE
Executive Director
Pharmacoepidemiology
Merck Research Laboratories

Setting the Baseline on Benefit-Risk Assessment

Richard A. Forshee, PhD
Associate Director for Research,
Office of Biostatistics & Epidemiology
CBER, FDA

Patient Engagement in the Context of Drug Development & Benefit-Risk Assessment

Marilyn A. Metcalf, PhD
Senior Director
Benefit-Risk Evaluation
GlaxoSmithKline

Q&A Discussion/Feedback between Conference Participants & Panel

10:00-10:30AM **REFRESHMENT BREAK AND NETWORKING**

10:30AM-12:15PM SESSION 2: APPROACHES TO PATIENT ENGAGEMENT IN BENEFIT-RISK ASSESSMENT THROUGHOUT THE PRODUCT LIFE CYCLE

SESSION CHAIRS

Rebecca A. Noel, DrPH, MPH
Global Benefit-Risk Lead
Global Patient Safety
Eli Lilly and Company

Cynthia Rice
Senior Vice President, Advocacy & Policy
JDRF

Drug development takes place in a highly regulated environment with development timelines built into the process. In this environment, how and when should patient engagement occur as benefits, risks, and balance are being assessed?

This session will go into deeper detail about the points during the product cycle at which benefits and risks are assessed and balanced. For each key point or stage, the group will discuss what decisions must be made, who are the stakeholders most involved, effective and cutting edge methods for expression of patient preferences and perspectives, approaches for patient engagement, objectives of communication among key stakeholders, and uncertainties around information used for assessment. The impact of uncertainty on decision-making processes, including the need to understand patient tolerance for uncertainty, will be explored in more detail.

Patient Engagement in the Development and Peri-approval Stages

Bray Patrick-Lake
Director of Stakeholder Engagement
Clinical Trials Transformation Initiative (CTTI)

Juhaeri Juhaeri, PhD
Head, Pharmacoepidemiology
Global Pharmacovigilance and Epidemiology
Sanofi

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

Patient Engagement in the Post-approval Stage

Richard Hermann, MD, MPH
Safety Science Physician
Global Patient Safety
AstraZeneca

Q&A

Patient Engagement in Individual Decision-Making

Liana Fraenkel, MD, MPH
Professor of Medicine
Yale University School of Medicine

Q&A

A Candid Conversation About Uncertainty

FDA Speaker Invited

Bray Patrick-Lake
Director of Stakeholder Engagement
Clinical Trials Transformation Initiative (CTTI)

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Executive Director
Pharmacoepidemiology
Merck Research Laboratories

Liana Fraenkel, MD, MPH
Professor of Medicine
Yale University School of Medicine

Patient Representative Invited

Q&A

12:15-1:15PM LUNCHEON AND NETWORKING

1:15-2:15PM SESSION 3: LEARNINGS FROM PATIENT ENGAGEMENT IN CLINICAL TRIALS AND OTHER TYPES OF HEALTH RESEARCH

SESSION CHAIRS

John F. P. Bridges, PhD
Associate Professor
Department of Health Policy & Management
Johns Hopkins Bloomberg School of Public Health

Kimberly McCleary
Director of Strategic Initiatives
FasterCures | A Center of the Milken Institute

Awareness of the importance of patient engagement in benefit-risk assessment and decision-making is growing, but there is still limited evidence about effective engagement practices. This session focuses on patient engagement in other aspects of the clinical trial, such as the qualification of patient-reported outcome measures (PROs), and in other types of health research, such as PCORI-funded research, and what can be learned from those experiences.

PANEL DISCUSSION

Darius Tandon, PhD
Associate Professor
Northwestern University Feinberg School of Medicine

Ari Gnanasakthy, MSc, MBA
Head, Patient Reported Outcomes
RTI Health Solutions

Susan dosReis, PhD
Associate Professor
Department of Pharmaceutical Health Services Research
University of Maryland School of Pharmacy

Q&A

2:15-3:15PM SESSION 4: CREATING A VISUAL MODEL FOR PATIENT ENGAGEMENT IN BENEFIT-RISK ASSESSMENT

SESSION CHAIRS

Elaine H. Morrato, DrPH, MPH, CPH
Associate Professor (with Tenure)
Department of Health Systems, Policy, & Management
Colorado School of Public Health, University of Colorado Anschutz Medical Campus

Meredith Y. Smith, PhD, MPA
Global Risk Management Officer
Global Patient Safety
Amgen

In this session, participants will interact with discussion and graphic facilitators to create a visual model of patient engagement in benefit-risk assessment and decision making at key points in the medical product life cycle. The engagement and input gathering processes at each point will be described within the context of patient needs and experience by exploring such questions as "Who are the multiple and changing stakeholders? What decisions must be made? How do factors like patient diversity, methodology limitations, availability of existing therapies, and others affect perspectives on benefit and risk?"

The visual model will be enhanced throughout the remainder of the conference as the group identifies effective approaches, barriers, and needs for research and change to better incorporate the patient voice in benefit-risk assessment and decision making.

3:15-3:45PM REFRESHMENT BREAK AND NETWORKING

3:45-5:30PM SESSION 5: PATIENT ENGAGEMENT IN BENEFIT-RISK ASSESSMENT: REGULATORY, METHODOLOGICAL, AND OPERATIONAL CHALLENGES AND GAPS

SESSION CHAIRS

Bennett Levitan, MD, PhD
Senior Director
Benefit-Risk Assessment
Department of Epidemiology
Janssen Research & Development

Tarek Hammad, MD, PhD, MS, MSc, FISPE
Executive Director
Pharmacoepidemiology
Merck Research Laboratories

This session will examine real-world implementation of patient engagement in benefit-risk assessment and will begin a deeper exploration with the group of methodological and operational challenges and how these may be addressed to assure the capture and incorporation of patient input. Special focus will be placed on the impact and accommodation of crosscutting factors such as what types of medical treatment/benefit-risk situations lend themselves to patient preference assessment, when in development should patient preferences be assessed, whose input should be elicited (e.g. group vs. individual input, experienced patients vs. the community at large), and how can heterogeneity in patient populations and their views be handled. Practical challenges for researchers, including managing diverse views within companies and across disciplines will also be discussed.

Cross-Cutting Considerations for Companies in the Regulated Environment

Bennett Levitan, MD, PhD
Senior Director
Benefit-Risk Assessment
Department of Epidemiology
Janssen Research & Development

Eliciting Patient Input – From Whom?

Meredith Y. Smith, PhD, MPA
Global Risk Management Officer
Global Patient Safety
Amgen

The Impact of Heterogeneity among Patient Populations

Marilyn A. Metcalf, PhD
Senior Director
Benefit-Risk Evaluation
GlaxoSmithKline

There will be a 10 minute Q&A with each speaker after their presentation.

5:30PM WRAP UP: ACCOMPLISHMENTS TODAY; WHAT WE'LL DO TOMORROW

6:00-7:00PM NETWORKING RECEPTION

FRIDAY, SEPTEMBER 18

7:15-8:15AM **REGISTRATION AND CONTINENTAL BREAKFAST**

8:15AM **WELCOME & GOALS FOR DAY 2**

8:30-10:00AM **SESSION 6: PATIENT ENGAGEMENT IN BENEFIT-RISK ASSESSMENT: REGULATORY CHALLENGES IN INTEGRATING QUANTITATIVE AND QUALITATIVE DATA INTO BENEFIT-RISK ASSESSMENTS**

SESSION CHAIRS

Tarek Hammad, MD, PhD, MS, MSc, FISPE
Executive Director
Pharmacoepidemiology
Merck Research Laboratories

F. Reed Johnson, PhD, MA
Senior Research Scholar
Center for Clinical and Genetic Economics
Duke Clinical Research Institute
Duke University

Currently, the medical product submission process in the US does not include a way to provide quantitative data on patient preferences and perspectives regarding benefit and risk, creating an imbalance between safety and efficacy considerations and benefit-risk balance considerations at regulatory decision time. There are recent indications that FDA is receptive to including such data in regulatory decision-making, and in this session, FDA staff from CDER (drugs/biologics) and CDRH (devices and diagnostics) will discuss progress on this issue. Quantitative versus qualitative approaches that might be used and special considerations for patient input on post-market safety information will also be examined. A panel of FDA speakers will interact with the conference participants to conclude this session.

Potential Role of Patients' Input in the Product Development & Approval Process

F. Reed Johnson, PhD, MA
Senior Research Scholar
Center for Clinical and Genetic Economics
Duke Clinical Research Institute
Duke University

FDA Plans to Utilize Patient-Elicited Data in Approval

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

Patient Safety Information Needed at Approval

Paul G. Kleutz, MD
Acting Deputy Director
Office of Hematology and Oncology Products
CDER, FDA

Quantitative vs Qualitative Approaches to Incorporating Patients' Input in the Approval Process

Lisa M. LaVange, PhD
Director
Office of Biostatistics, Office of Translational Sciences, CDER
FDA

Considerations in Using Patient Preference Information in the Regulatory Process

Telba Irony, PhD
Chief
Biostatistics: General Surgical Devices Branch, CDRH
FDA

Q&A with FDA Panelists

10:00-10:30AM **REFRESHMENT BREAK AND NETWORKING**

10:30-11:30AM SESSION 7: EQUIPPING PATIENT PARTNERS TO PROVIDE INPUT

SESSION CHAIRS

Richard Hermann, MD, MPH
Safety Science Physician
Global Patient Safety
AstraZeneca

Kimberly McCleary
Director of Strategic Initiatives
FasterCures | A Center of the Milken Institute

Patient partners have significant contributions to make in benefit-risk assessment and decision-making, and a clear understanding of the medical product life cycle process helps to enable their proactive involvement. Recognizing the unique and varied knowledge and experience of patient partners, this session will discuss model initiatives to provide knowledge resources for patient partners.

Research-Ready Populations

Marc M. Boutin
Chief Executive Officer
National Health Council (NHC)

FDA Patient Education and Training Efforts

Richard Klein
Director
Patient Network Program, Office of Health and Constituent Affairs,
Office of the Commissioner
FDA

Utilizing Technology: Online Patient Platforms

Sara Loud, MSEE, MBA
Chief Operating Officer
Accelerated Cure Project for Multiple Sclerosis
Co-principal Investigator, iConquerMS™

Panel Q&A

11:30AM-12:45PM SESSION 8: MAXIMIZING PATIENT IMPACT ON BENEFIT-RISK ASSESSMENT: PATIENT-INITIATED MODELS FOR COLLECTING PATIENT PERSPECTIVES

SESSION CHAIRS

Patricia Furlong, BSN
Founding President and CEO
Parent Project Muscular Dystrophy

Cynthia Rice
Senior Vice President
Advocacy & Policy
JDRF

This session will feature patient partner initiatives to collect perspectives of their patient communities on benefit and risk considerations. The initiatives presented will highlight the impact of characteristics of the patient community and of the treatment life cycle stage on objectives and approaches of these patient partners. The conference participants will engage in a full group discussion of the presented projects and ideas or awareness of other novel approaches.

Duchenne Muscular Dystrophy: The Power of Patient Input to Influence Drug Development Decisions

Holly Peay, PhD, CGC
RTI International
PI, DuchenneConnect PCORnet Network

Diabetes – Building a Culture of Patient Engagement to Inform Regulatory Decisions

Cynthia Rice
Senior Vice President
Advocacy & Policy
JDRF

Kelly L. Close
President
Close Concerns
Founder, The diaTribe Foundation
Video presentation

Alain Silk, MD
Reviewer, Division of Chemistry and Toxicology Devices
CDRH
FDA

Patient Engagement During the Post-Approval Phase

Carmen Bozic, PhD
Senior Vice President, Global Development
Biogen

Q&A

12:45-1:45PM LUNCHEON AND ROUNDTABLE DISCUSSIONS

Roundtable Discussions: "Brainstorm of Other Novel Approaches" to be held during lunch. Join the roundtable discussions on Twitter with #DIAEngagePM.

There will be no formal afternoon break, however, continuous refreshments will be available throughout the afternoon

1:45-3:45PM SESSION 9: REVISITING THE "VISUAL MODEL" FOR PATIENT ENGAGEMENT IN BENEFIT-RISK ASSESSMENT

SESSION CHAIRS

Elaine H. Morrato, DrPH, MPH, CPH
Associate Professor (with Tenure)
Department of Health Systems, Policy, & Management
Colorado School of Public Health, University of Colorado
Anschutz Medical Campus

Meredith Y. Smith, PhD, MPA
Global Risk Management Officer
Global Patient Safety
Amgen

In this session, small groups will examine the benefit-risk assessment visual model as it looks at the close of Session 8. Using smaller replicas of the model at their tables, groups may add further perspectives on process, challenges, barriers, and areas needing improvement.

The larger group will then reconvene for a facilitated discussion on "How should a well-functioning system of gathering and considering patient input work?" Significant challenges, gaps in knowledge, and areas that must be improved will be captured in the model, along with stakeholders' roles and suggested next steps for improvement.

3:45-4:15PM SESSION 10: SUMMATION AND CALL TO ACTION

Reflecting on the presentations and discussions of the past two days, a panel of stakeholders will highlight key learnings and agreements about including the patient perspective in benefit-risk assessment and decision-making through the medical product life cycle.

The closing Keynote Presentation will outline the vision and a call to action for better outcomes for patients through the collaborative efforts of all stakeholders.

Highlights of Key Conference Learnings and Agreements

Panelists Invited

Closing Keynote Speaker

Robert M. Califf, MD
Deputy Commissioner
Office of Medical Products and Tobacco
FDA

Brief Closing Remarks

Barbara Lopez Kunz
Global Chief Executive
DIA

4:15PM CONFERENCE ADJOURNS

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