



Princeton Marriott at Forrestal
100 College Road East
Princeton, NJ 08540



2016 Summit USA Agenda

The Avoca Quality Consortium

May 10, 2016

AQC Members-Only Meeting and Industry-Wide Afternoon Workshops

8:15 AM - 9:00 AM

REGISTRATION AND CONTINENTAL BREAKFAST

9:00 AM - 9:30 AM

WELCOME AND OVERVIEW OF THE DAY – INTRODUCTION, REVIEW AGENDA, AND OBJECTIVES



Speakers:

Patricia Leuchten, President & CEO, The Avoca Group

Steve Whittaker, Executive Director, Avoca Quality Consortium, The Avoca Group

9:30 AM - 10:15 AM

SESSION 1: "CONNECTING THE DOTS": A LOOK AT EXISTING TOOLS AND PORTAL ENHANCEMENTS TO ENSURE OPTIMIZATION OF AQC LEADING PRACTICES



Speaker:

Lakshmi Sundar, Vice President, Strategy and Development, The Avoca Group

10:15 AM - 11:00 AM

SESSION 2: WEAVING PATIENT CENTRICITY AND QUALITY INTO NEXT GEN PROTOCOL DEVELOPMENT



Speakers:

Denise Calaprice, PhD, Senior Consultant, The Avoca Group

Steve Whittaker, Executive Director, Avoca Quality Consortium, The Avoca Group

11:00 AM - 11:30 AM

NETWORKING BREAK

11:30 AM - 12:15 PM

SESSION 3: ELI LILLY CASE STUDY – A PATIENT CENTRIC APPROACH TO IMPROVING THE QUALITY OF TRIAL EXECUTION THROUGH TRIAL SIMULATIONS AND SITE ADVOCACY GROUPS

Speaker:

Joseph Kim, MBA, Senior Advisor, Clinical Innovation, Eli Lilly and Co.

12:15 PM - 1:00 PM

SESSION 4: QUALITY WITHOUT BORDERS: OPERATIONALIZING AN INTEGRATED RISK-BASED APPROACH FOR INSPECTION READINESS

Moderators:

Steve Whittaker, Executive Director, Avoca Quality Consortium, The Avoca Group

Karin Daun, Senior Consultant, The Avoca Group

Industry Expert:

Joanne Spallone, Global Head, Clinical Development Quality Assurance, Novartis

1:00 PM - 2:00 PM

NETWORKING LUNCH

2:00 PM - 5:00 PM

PRE-CONFERENCE WORKSHOPS

WORKSHOP 1: IMPROVE THE EFFICIENCY & QUALITY OF CLINICAL TRIAL DESIGN BY REIMAGINING PATIENT ENGAGEMENT USING DESIGN THINKING

Speaker:

Drew Marshall, Founder and Principal, Primed Associates

WORKSHOP 2: CREATING AND IMPLEMENTING AN EFFECTIVE SPONSOR/CRO QUALITY OVERSIGHT PLAN TO ACHIEVE YOUR CLINICAL OPERATIONS GOALS

Speakers:

Janis Hall, Senior Consultant, The Avoca Group

Caryn Laermer, Associate Director, Avoca Quality Consortium, The Avoca Group

Grace Crawford, Vice President, Clinical Quality & Compliance, MedImmune

WORKSHOP 3: DEVELOPING HIGH-VALUE CLINICAL TRIAL QUALITY PERFORMANCE MEASURES

Speakers:

Jonathan Rowe, PhD, Head of Quality Performance and Risk Management, Pfizer
Armelde Pitre, Senior Director, Quality Performance and Risk Management and Analytics, Pfizer
Denise Calaprice, PhD, Senior Consultant, The Avoca Group

6:00 PM

DINNER AT GRATELLA, SPONSORED BY ACURIAN

May 11, 2016

Full Day Open to the Industry

7:30 AM

NETWORKING BREAKFAST

8:30 AM

WELCOMING REMARKS

Speakers:

Patricia Leuchten, President & CEO, The Avoca Group
Robert Metcalf, PhD, Vice President, Global Regulatory Affairs – NA and Clinical Quality, Eli Lilly and Co.

9:00 AM

THE POWER OF COLLABORATIVE PARTNERSHIPS TO INCREASE CLINICAL TRIAL QUALITY

Moderator:

Robert Metcalf, PhD, Vice President, Global Regulatory Affairs – NA and Clinical Quality, Eli Lilly and Co.

Panelists:

Elspeth Carnan, PhD, Head of R&D Operational Excellence, Sunovion
Peter Aurup, MD, Head, Global Development Operations, Pharmacyclics
Eric Terhaerd, Senior Vice President, Global Development Operations, Astellas
Amy Y. Grahn, MS, Senior Vice President, Clinical Development and Operations, Horizon Pharma
Susan Romberg, Vice President, Global Clinical Development, North America, Chiltern
Kenneth A. Somberg, MD, MBA, Vice President and Chief Medical Officer, Covance

10:00 AM
NETWORKING BREAK

10:30 AM
ASSESSING RETURN ON PATIENT CENTRIC ENGAGEMENT INITIATIVES:
REVIEW AND DISCUSSION OF THE TUFTS CSDD-DIA WORKING GROUP
STUDY RESULTS

 **Speaker:**

Kenneth Getz, Director and Associate Professor, Tufts CSDD

11:15 AM
FOLLOW-UP PANEL – MULTI-STAKEHOLDER PERSPECTIVES ON PATIENT-
CENTRICITY AND ITS IMPACT ON QUALITY

 **Moderator:**

Kenneth Getz, Director and Associate Professor, Tufts CSDD

Panelists:

Kathleen Griffin, Executive Director, Corporate Strategy, INC Research

Paulo Moreira, Vice President, Global Clinical Operations – External Innovation, EMD Serono

Marta Fields, Senior Director, Compliance and Quality Systems, Seattle Genetics

Matthew Howes, Executive Vice President, Strategy & Growth, PALIO, an inVentiv Health company

12:00 PM
LUNCH & ROUNDTABLE DISCUSSIONS

1:15 PM
KEYNOTE SPEAKER: PATIENTS AS MICRO-EXPERTS: ENHANCING CLINICAL
RESEARCH BY SEEING PATIENTS AS COLLABORATORS

 **Speaker:**

Roni Zeiger, MD, Former Chief Health Strategist at Google, Co-Founder & CEO, Smart Patients

1:45 PM
MODERATED DISCUSSION ON PATIENT CENTRICITY

 **Moderator:**

Jeffrey S. Kasher, PhD, Founder, Patients Can't Wait

Panelists:

Roni Zeiger, MD, Former Chief Health Strategist at Google, Co-Founder & CEO, Smart Patients

Craig Lipset, Head of Clinical Innovation, Pfizer

Marc Foster, Co-Founder, Chief Operating Officer, Transparency Life Sciences

2:15 PM**CASE STUDY ON THE USE OF WEARABLE DEVICES IN CLINICAL RESEARCH****Speakers:**

Jeremy Gilbert, MBA, Vice President of Product & Strategy, PatientsLikeMe

Jane Rhodes, PhD, MBA, Senior Director, New Initiatives, Innovation Hub, Biogen

2:45 PM**NETWORKING BREAK****3:15 PM****INNOVATIVE COLLABORATIONS IN THE DESIGN AND INTEGRATION OF QUALITY IN CLINICAL OPERATIONS****Moderator:**

Robert Metcalf, PhD, Vice President, Global Regulatory Affairs – NA and Clinical Quality, Eli Lilly and Co.

Panelists:

Grace Crawford, Vice President, Clinical Quality & Compliance, MedImmune

Neil McCullough, PhD, MSc, Executive Vice President, Quality Assurance, ICON

Paul Gilbert, Co-Founder and CEO, MedAvante

4:00 PM**20/20 VISION: FUTURE OF CLINICAL RESEARCH****Moderator:**

Craig Lipset, Head of Clinical Innovation, Pfizer

Panelists:

Jennifer Byrne, CEO, PMG Research

Anthony J. Costello, Chief Executive Officer, Mytrus

Jeffrey S. Kasher, PhD, Founder, Patients Can't Wait

Mitchell Katz, PhD, Head of Medical Research & Drug Safety Operations, Purdue Pharma

Reb Tayyabkhan, Head of Central Clinical Services, Bristol-Myers Squibb

5:30 PM**CLOSING REMARKS****5:30 PM - 7:30 PM****COCKTAIL RECEPTION**