



AQC 2017 Summit USA

May 10 & 11, 2017

Kimpton Hotel Eventi
New York City, New York

Wednesday, May 10, 2017 (MEMBERS ONLY)

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| 8:30am – 9:00am | Registration and Continental Breakfast |
| 9:00am – 9:30am | Welcoming Remarks |
| 9:30am – 11:00am | <p>Interactive Workshop – Mapping the Current State of The Clinical Trial Landscape and Visualizing the Future</p> <p><i>The lens through which we view the world shapes how we think and respond to what happens around us. Author and business consultant, Merrick Rosenberg, will lead an engaging exercise in which we examine the clinical trial landscape. By linking clinical trials to powerful metaphors, Rosenberg believes we can understand where our thinking is constrained – and where it holds new possibilities for innovation.</i></p> <ul style="list-style-type: none">• Merrick Rosenberg, Chief Executive Officer, Team Builders Plus |
| 11:00am – 11:30am | Networking Break |
| 11:30am – 12:45pm | <p>Interactive Workshop – An Empowerment Journey on Imagining the Personal Possibilities for Making a Difference to the Clinical Trial Landscape</p> <p><i>Building on the previous session with Merrick Rosenberg, the best-selling author Mark Matousek will lead a workshop to convert its outcomes into practical action. Matousek believes that the stories we tell guide the actions we take. By improving our stories, we can improve the outcomes we achieve.</i></p> <ul style="list-style-type: none">• Mark Matousek, President, Mark Matousek Media |
| 12:45pm – 2:00pm | Networking Lunch – Moderated Roundtables |
| 2:00pm – 2:20pm | The Changing Landscape of Risk – <i>From reactive to proactive assessment and management</i> |
| 2:20pm – 2:30pm | Transition to Workshops |

- 2:30pm – 3:30pm** Part 1: Afternoon Workshops (Pick 1 of 2)
- Workshop 1: Inspections in the Landscape of Risk
 - Workshop 2: Patients – Incorporating Input and Optimizing Engagement (*A limited capacity Executive roundtable*)
- 3:30pm – 3:50pm** Networking Break
- 3:50pm – 4:50pm** Part 2: Afternoon Workshops (Pick 1 of 2)
- Workshop 3: The Evolving World of Oversight
 - Workshop 4: Metrics – Risk Framework that Maps Metrics to Risk Management and Decisions
- 5:30pm** Cocktail Reception
- 6:30pm** Member Dinner, sponsored by inVentiv Health

Thursday, May 11, 2017 (OPEN TO INDUSTRY)

Emcee: **Coleen Glessner**, *Senior Vice President, Chief Quality Officer, Alexion*

- 8:00am – 8:30am** Registration and Continental Breakfast
- 8:30am – 9:00am** Welcoming Remarks
- 9:00am – 9:45am** Keynote Address – Changing Landscapes – Pivoting from the Present to the Future
- **John Foley**, *Founder & Chief Executive Officer, John Foley, Inc.*
Former lead solo pilot of the Blue Angels, a Sloan Fellow at Stanford School of Business, a gratitude guru and an expert on building High Performance teams

- 9:45am – 10:45am** Innovative Partnering Models – Transforming Partnerships to a Higher Level of Innovation and Efficiency
- Moderator:
- **Robert Metcalf, PhD**, *Vice President, MDU Diabetes and Clinical Transformation, Eli Lilly and Company*
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- **John Foley**, *Founder & Chief Executive Officer, John Foley, Inc.*
 - **Coleen Glessner**, *Senior Vice President, Chief Quality Officer, Alexion*
 - **Jeff James**, *Executive Vice President, Alliance Management, ICON*
 - **Andy Lee**, *Senior Vice President, Head of Global Clinical Trial Operations, Merck*
 - **Adrian Otte, MB, BCh, FFPM**, *Vice President Global Development Operations, Amgen*
- 10:45am – 11:15am** Networking Break
- 11:15am – 11:30am** The Importance of Patient Engagement – *A Mom’s Experience Harnessing Data to Benefit Her Kids and Beyond*
- **Denise Calaprice, PhD**, *Senior Consultant, The Avoca Group*
- 11:30am – 12:15pm** Patient Engagement – *A practical approach to incorporating the patient perspective before, during, and post clinical trials*
- Moderator:
- **Lakshmi Sundar**, *Vice President, Strategy and Development, The Avoca Group*
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- **Denise Calaprice, PhD**, *Senior Consultant, The Avoca Group*
 - **Rhonda Henry**, *Vice President, Site Networks and Patient Centricity, PPD*
 - **Mitchell A. Katz, PhD**, *Head of Clinical Research & Drug Safety Operations, Purdue Pharma*
 - **Paulo Moreira**, *Vice President, Global Clinical Operations - External Innovation, EMD Serono*
 - **Roni Zeiger, MD**, *Former Chief Health Strategist at Google, Co-Founder and Chief Executive Officer, Smart Patients*
- 12:15pm – 1:30pm** Networking Lunch, sponsored by Purdue Pharma
- 1:30pm – 2:00pm** Reframing Risk Management as a Decision-Making Process
- **Brian W. Hagen, PhD**, *Founder and Managing Director, Decision Empowerment Institute*

2:00pm – 2:45pm

Risk-Based Decision-Making – *Needs for transforming human capital management and improving risk mitigation in clinical trial execution*

Moderator:

- **Mark Matousek**, *President, Mark Matousek Media*
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- **Brian W. Hagen, PhD**, *Founder and Managing Director, Decision Empowerment Institute*
 - **Jessica Lee, MS, MPH**, *Vice President, Clinical Operations and Compliance, Inovio*
 - **Neil McCullough, PhD, MSc**, *Executive Vice President, Quality and Compliance, ICON*
 - **Robert Metcalf, PhD**, *Vice President, MDU Diabetes and Clinical Transformation, Eli Lilly and Company*

2:45pm – 3:15pm

Networking Break

3:15pm – 3:45pm

Interactive Discussion – Moving Toward Greater Efficiency and Transformation in Clinical Trial Execution – *What is Holding Us Back?*

- **Patricia Leuchten**, *President and Chief Executive Officer, The Avoca Group*
- **Ibraheem Mahmood**, *President and Chief Executive Officer, DrugDev*

3:45pm – 4:30pm

Moving from Technology as an Enabler to a Game Changer

Moderator:

- **Steve Whittaker**, *Executive Director, Avoca Quality Consortium, The Avoca Group*
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- **Dimitris K. Agrafiotis, PhD, FRSC**, *Chief Data Officer, Covance*
 - **Paul Gilbert**, *Co-Founder & Chief Executive Officer, MedAvante*
 - **John Hubbard, PhD, FCP**, *President, Chief Executive Officer and Member of the Board of Directors, Bioclinica*
 - **Jake LaPorte, PhD**, *Head of Digital Development and Strategic Assistant to Global Head of Portfolio Strategy & Innovation, Novartis*
 - **Jonathan Lee**, *Vice President, Development Operations, Cidara Therapeutics*

4:30pm – 4:45pm

Call to Action