

EMBRACE | OWN THE THE PRESENT | FUTURE

7TH ANNUAL AQC GLOBAL QUALITY SUMMIT
13-14 June 2018 | Dublin, Ireland

AGENDA - DAY 1

WEDNESDAY, 13 JUNE

9:45 – 10:30

REGISTRATION AND LIGHT REFRESHMENTS

10:30 – 12:00

PRE-CONFERENCE WORKSHOP

AQC's additions, improvements, and changes.

- Site Centricity
- Inspection Readiness
- New Prequalification Standards
- Clinical Trials of the Future
- Risk Management and ICH E6 (R2)
- eLuminate™ Online Learning Platform

▶ **Crissy MacDonald**, Executive Director, Client Delivery, Avoca Quality Consortium

▶ **Irene Catherine Michas**, Senior Consultant, The Avoca Group

▶ **Steve Whittaker**, Executive Director, Avoca Quality Consortium

12:00 – 13:30

WELCOME LUNCHEON



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Bringing efficiency, quality, and risk mitigation
to the forefront of clinical trials.

AGENDA - DAY 1

13:30 – 14:00

WELCOMING REMARKS AND INTRODUCTION

- ▶ **Patricia Leuchten**, *Founder and Chief Executive Officer, The Avoca Group*
- ▶ **Steve Whittaker**, *Executive Director, Avoca Quality Consortium*

14:00 – 14:45

THE FUTURE OF ENGAGEMENT

Creating a culture of quality within virtual teams.

- ▶ **Karen Lojeski**, *Chief Executive Officer, Virtual Distance*

14:45 – 15:15

NETWORKING BREAK

15:15 – 16:30

WORKSHOP: TODAY'S DECISIONS, TOMORROW'S OUTCOMES

Risk-mitigation and ICH E6 (R2)'s impact on pharma's definition of "business as usual".

- ▶ **Jonathan Rowe**, *Executive Director, Head of Clinical Development Quality Performance and Risk Management, Pfizer*
- ▶ **Steve Whittaker**, *Executive Director, Avoca Quality Consortium*

16:30 – 16:55

QUALIFYING THE FUTURE

Diligent® is reimagining how qualifying vendors will look in the future to help decrease lead time to select new vendors.

- ▶ **Jeffrey Kasher**, *Executive Chair, Avoca Quality Consortium*
- ▶ **Dennis Salotti**, *Chief Operating Officer, The Avoca Group*

16:55 – 17:00

CLOSING REMARKS

18:30

COCKTAIL RECEPTION AND DINNER

18:30 - Shuttle departs from Hotel InterContinental to Teeling Whiskey Distillery

19:00 - Tour and Tasting

20:00 - Dinner



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AGENDA - DAY 2

THURSDAY, 14 JUNE

7:45 – 8:30

REGISTRATION AND NETWORKING BREAKFAST

8:30 – 9:00

WELCOMING REMARKS

- ▶ **Patricia Leuchten**, *Founder and Chief Executive Officer, The Avoca Group*
- ▶ **Neil McCullough**, *Executive Vice President, Quality & Compliance, ICON*
- ▶ **Jonathan Rowe**, *Executive Director, Head of Clinical Development Quality Performance and Risk Management, Pfizer*

9:00 – 9:45

A SOFT LANDING INTO THE FUTURE

Healthcare is facing changes in almost every aspect of its processes. Technology is pushing, patients are demanding, and sustainability is under pressure.

- ▶ **Lucien Engelen**, *Director Radboud University Medical Center's REshape Center for Innovation; Global Strategist Digital Health Deloitte Center for the Edge, Faculty Singularity University Silicon Valley and The Netherlands*

9:45 – 10:45

PANEL DISCUSSION: PLANNING FOR QUALITY WITH AN UNCERTAIN FUTURE

Key executives will diagnose the current gaps in the industry and their perspectives on regulatory constraints, complexity of clinical trials, and the current industry approach to conducting clinical trials.

MODERATOR

- ▶ **Jeffrey Kasher**, *Executive Chair, Avoca Quality Consortium*

PANELISTS

- ▶ **Lucien Engelen**, *Director Radboud University Medical Center's REshape Center for Innovation; Global Strategist Digital Health Deloitte Center for the Edge, Faculty Singularity University Silicon Valley and The Netherlands*
- ▶ **Tanja Keiper**, *Director, GCO External Innovation/Clinical Applications & Innovation, Biopharma, Merck KGaA (EMD Serono)*
- ▶ **Neil McCullough**, *Executive Vice President, Quality & Compliance, ICON*
- ▶ **Jonathan Rowe**, *Executive Director, Head of Clinical Development Quality Performance and Risk Management, Pfizer*

10:45 – 11:20

NETWORKING BREAK



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AGENDA - DAY 2

11:20 – 12:30

PANEL DISCUSSION: THE GROWING COMPLEXITY OF THE CLINICAL TRIAL ECOSYSTEM

The disconnect within key players of the clinical trial ecosystem and how reducing the variability in clinical trial execution will increase the quality of the industry.

MODERATOR

- ▶ **Steve Whittaker**, Executive Director, Avoca Quality Consortium

PANELISTS

- ▶ **Evjatar (Evi) Cohen**, Vice President, Global Life Sciences - Pharma/Biotech & Medical Devices, Appian Corporation
- ▶ **Nona Dokuzova**, Head, Global Quality Compliance, Biopharma, Global Research and Development Quality (RDQ), Merck KGaA (EMD Serono)
- ▶ **Patty Donnelly**, Vice President, Research and Development Quality, Eli Lilly and Company
- ▶ **Rose Kidd**, Senior Vice President, Global Clinical Operations, ICON
- ▶ **Jim Kremidas**, Executive Director, The Association of Clinical Research Professionals (ACRP)

12:30 – 13:45

LUNCH

Sponsored by Purdue Pharma

13:45 – 14:45

EMBRACE THE PRESENT, DESIGN THE FUTURE

Behaviors of innovative cultures. How to take ideas of the future and make them goals for today.

- ▶ **Merrick Rosenberg**, Chief Executive Officer, Take Flight Learning

14:45 – 15:15

CLINICAL STUDY CONDUCT TRENDS

Outline of key trends driving the clinical research landscape.

- ▶ **Kenneth Getz**, Director, Sponsored Research Programs, Associate Professor, Tufts CSDD, Tufts University School of Medicine

15:15 – 15:35

NETWORKING BREAK



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AGENDA - DAY 2

15:35 – 15:55

PATIENTS WITH POWER

A pharmaceutical colleague's experience as a melanoma patient in a clinical trial and the evolving role of patients in the design and conduct of clinical trials.

- ▶ **Imogen Cheese**, *European Director, Business Development, Imperial Clinical Research Support*

15:55 – 16:45

PANEL DISCUSSION: EMBRACING THE EVOLVING ROLE OF THE PATIENT

Experts discuss how the future of clinical trials will be affected by patients who have access to better technologies and information in their search for a treatment or cure.

MODERATOR

- ▶ **Imogen Cheese**, *European Director, Business Development, Imperial Clinical Research Support*

PANELISTS

- ▶ **Kenneth Getz**, *Director, Sponsored Research Programs, Associate Professor, Tufts CSDD, Tufts University School of Medicine*
- ▶ **Jim Lane**, *Chief Business Officer, Longboat*
- ▶ **Suzanne Murray**, *Vice President of Quality, Agios Pharmaceuticals*
- ▶ **Dennis Salotti**, *Chief Operating Officer, The Avoca Group*

16:45 – 17:00

CLOSING

17:30

SUMMIT CLOSING EVENT SPONSORED BY LONGBOAT CLINICAL

Sea2Summit - Dinner and pub tour along Dublin's magnificent coastline

17:30 - Shuttle departs from Hotel InterContinental

24:00 - Shuttle returns



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