

OWN THE FUTURE

8TH ANNUAL AVOCA GLOBAL SUMMIT

June 5-6, 2019 | BOSTON, MA

AGENDA - DAY 1

WEDNESDAY, JUNE 5

9:45 am – 10:30 am

REGISTRATION AND NETWORKING BREAKFAST

10:30 am – 12:00 pm

PRE-CONFERENCE WORKSHOP

AQC Workstream Updates

- Site Centricity
- Inspection Readiness
- Provider Qualification
- Risk-Based Quality Management

▶ **Steve Whittaker**, Senior Consultant, The Avoca Group

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

▶ **Janis Hall**, Senior Consultant, The Avoca Group

12:00 pm – 1:00 pm

WELCOME LUNCHEON – SPONSORED BY LONGBOAT

1:00 pm – 1:45 pm

OPENING REMARKS AND INTERACTIVE DISCUSSION

▶ **Patricia Leuchten**, Founder and CEO, The Avoca Group

▶ **Jonathan Rowe**, Executive Director, Head of Clinical Development Quality Performance and Risk Management, Pfizer

▶ **Steve Whittaker**, Senior Consultant, The Avoca Group

AGENDA - DAY 1

1:45 pm – 2:00 pm

ACRP/AQC WORKFORCE COMPETENCY INITIATIVES

- ▶ **Jim Kremidas**, *Executive Director, Association of Clinical Research Professionals (ACRP)*

2:00 pm – 2:10 pm

TRANSITION INTO WORKSHOPS

2:10 pm – 3:20 pm

CHOOSE WORKSHOP 1A OR 1B:

Workshop 1A: Quality Tolerance Limits

Unraveling the mystery of QTLs. This hands-on, deep-dive workshop will help participants gain clarity on terminology, metrics, performance indicators, and tolerance limits. It will provide insights about relevant clinical trial parameters that merit QTLs, approaches to establish appropriate limits, and methodology for monitoring and controlling study activities to minimize risk and likelihood to reach tolerance limits that warrant action.

- ▶ **Steve Whittaker**, *Senior Consultant, The Avoca Group*
- ▶ **Lenna Kimball**, *Vice President, Clinical Operations, Lyell Immunopharma*
- ▶ **Jonathan Rowe**, *Executive Director, Head of Clinical Development Quality Performance and Risk Management, Pfizer*

Workshop 1B: Risk-Based Inspection Readiness

Participants will explore ideas for adapting existing tools that can be used proactively throughout a clinical study as well as at different points during inspection preparation. The format aims to stimulate thinking about ways to promote a culture of quality and proactive risk-based inspection readiness within organizations, e.g. through the development and/or adaptation of existing inspection preparation tools and their effective implementation.

- ▶ **Irene Michas**, *Senior Consultant, The Avoca Group*
- ▶ **Joe Fortunato**, *Senior Director, Client Delivery, The Avoca Group*

3:20 pm – 3:45 pm

NETWORKING BREAK

AGENDA - DAY 1

3:45 pm – 4:55 pm

CHOOSE WORKSHOP 2A OR 2B:

Workshop 2A: Enhancing Site Quality

Takeda and Longboat will present a case study on how improvements in process and technology can better support sites, reducing their burden and therefore enhancing quality. The case study will highlight how the development of an online prescreening tool resulted in improved metrics and capability at sites across a program of studies. The session will include interactive discussions on how the concepts of the iterative development process can improve other aspects of site workflow.

- ▶ **Aidan Gannon**, *Head of Innovation and Client Services*, Longboat
- ▶ **Samantha Rogers**, *Patient Recruitment and Retention Lead*, Takeda
- ▶ **Steve Whittaker**, *Senior Consultant*, The Avoca Group

Workshop 2B: De-Mystifying Decentralized Clinical Trial Provider Qualification (Members Only)

Avoca's work in provider qualification has taken a turn to help the industry qualify providers who support Decentralized Clinical Trials through the use of mobile technologies (for data/document capture) or mobile services (for home Health Care Provider visits, telemedicine). Learn about how these technologies and services will transform future clinical trials and what to consider when qualifying vendors in the current climate of uncertainty in regulatory requirement interpretation.

- ▶ **Janis Hall**, *Senior Consultant*, The Avoca Group
- ▶ **John Jordan**, *Senior Vice President*, Product Development, Diligent Pharma

4:55 pm – 5:00 pm

CLOSING REMARKS

- ▶ **Caryn Laermer**, *Executive Director, Client Engagement*, The Avoca Group
- ▶ **Steve Whittaker**, *Senior Consultant*, The Avoca Group

6:00 pm – 6:30 pm

SHUTTLE DEPARTS FROM BOSTON HARBOR HOTEL TO LEGAL HARBORSIDE

6:30 pm – 9:00 pm

THE AVOCA GROUP'S 20TH ANNIVERSARY CELEBRATION AT LEGAL HARBORSIDE (dinner and cocktails; casual attire)

8:30 pm – 9:00 pm

SHUTTLE DEPARTS FROM LEGAL HARBORSIDE TO BOSTON HARBOR HOTEL

OWN THE FUTURE

8TH ANNUAL AVOCA GLOBAL SUMMIT

June 5-6, 2019 | BOSTON, MA

AGENDA - DAY 2

THURSDAY, JUNE 6

SUMMIT EMCEE

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

7:45 am – 8:30 am

REGISTRATION AND NETWORKING BREAKFAST – SPONSORED BY ORACLE HEALTH SCIENCES

8:30 am – 9:00 am

WELCOME AND OPENING REMARKS

- ▶ **Steve Whittaker**, Senior Consultant, The Avoca Group
- ▶ **Patricia Leuchten**, Founder and CEO, The Avoca Group
- ▶ **Patty Donnelly**, Vice President, Global Quality – Research and Development, Eli Lilly and Company

9:00 am – 9:10 am

INTRODUCTION OF KEYNOTE SPEAKER

Verizon Media's role in technology for life sciences

- ▶ **Brian Burk**, Life Science & Healthcare Innovation Practice Leader, Verizon Media

AGENDA - DAY 2

9:10 am – 10:00 am

KEYNOTE ADDRESS

Avoca is pleased to welcome David Shing “Shingy” as 2019’s Keynote Speaker. By day, Shingy is Verizon Media’s digital prophet, working across the globe to identify new opportunities for the business. David will discuss current and future trends in the evolving digital landscape, including how the rapid adoption of technology will advance the work of the clinical trials industry. He will also provide insight into what the industry’s most valued stakeholder, the patient, will expect from clinical trials. David has served as AOL’s European Head of Media and Marketing before taking on his current mantle in NYC.

- ▶ **David Shing**, Digital Prophet, Verizon Media

10:00 am – 10:30 am

RUNNING A DIGITAL CLINICAL TRIAL: THE FUTURE IS NOW

A look at how clinical trials are changing in light of new technologies and what we can anticipate as an industry.

- ▶ **Chen Admati**, Head of Intel Pharma Analytics Platform, Intel Corporation

10:30 am – 11:00 am

NETWORKING BREAK

11:00 am – 12:00 pm

PANEL DISCUSSION: OWNING THE FUTURE

What were once considered “Clinical Trials of the Future” are now the clinical trials of today. What are we learning about risk management and mitigation as this new wave of technologies implement themselves into clinical trial execution?

MODERATOR

- ▶ **Joseph Kim**, Senior Advisor, Clinical Operations, Transformational Technology and Innovation, Eli Lilly and Company

PANELISTS

- ▶ **Chen Admati**, Head of Intel Pharma Analytics Platform, Intel Corporation
- ▶ **Beatrice Anduze-Faris**, Executive Director, Head of Global Clinical Compliance and Continuous Improvement, Global Clinical Operations, Bristol-Myers Squibb
- ▶ **Steven Rosenberg**, Senior Vice President and General Manager, Oracle Health Sciences
- ▶ **David Shing**, Digital Prophet, Verizon Media

AGENDA - DAY 2

12:00 pm – 1:30 pm

LUNCH - SPONSORED BY VERIZON MEDIA

1:30 pm – 2:00 pm

THOUGHT LEADER SPOTLIGHT

A one-on-one interview on the state of clinical trials.

INTERVIEWEE:

- ▶ **Tom Pike**, Former CEO, Quintiles

INTERVIEWER:

- ▶ **Patricia Leuchten**, Founder and CEO, The Avoca Group

2:00 pm – 2:40 pm

INDUSTRY CHALLENGES WITH PROVIDER QUALIFICATION: WHAT'S AT STAKE?

A review of the Tufts-Avoca working group study design and interactive discussion.

- ▶ **Jay Turpen**, Senior Consultant, The Avoca Group
- ▶ **Ken Getz**, Director of Sponsored Programs and Associate Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine

2:40 pm – 3:10 pm

NETWORKING BREAK

3:10 pm – 3:30 pm

THOUGHT LEADER SPOTLIGHT

A one-on-one interview on the intersection between clinical trials and patient care.

INTERVIEWEE:

- ▶ **Jennifer Byrne**, CEO and Board Chair, Javara

INTERVIEWER:

- ▶ **Patricia Leuchten**, Founder and CEO, The Avoca Group

AGENDA - DAY 2

3:30 pm – 4:20 pm

PANEL DISCUSSION: FUTURE OF CLINICAL TRIAL PATIENT EXPERIENCE WITH USE OF DIGITAL TECHNOLOGY

Experts discuss how far we have come as an industry in terms of clinical research merging with patient care and how technology is impacting the patient experience today. 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:

- ▶ **Jennifer Byrne**, CEO and Board Chair, Javara

PANELISTS:

- ▶ **Bree Burks**, Senior Director, Vanderbilt Institute for Clinical and Translational Research, Vanderbilt University Medical Center
- ▶ **Ken Getz**, Director of Sponsored Programs and Associate Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine
- ▶ **Alexis Nichols Gordon**, Community Health Systems Infrastructure Project Manager, IDR, Inc., and Clinical Trial Patient
- ▶ **Elizabeth Luczak**, Vice President, Vertex Quality Assurance, Vertex Pharmaceuticals

4:20 pm – 4:30 pm

CLOSING REMARKS

- ▶ **Jonathan Rowe**, Executive Director, Head of Clinical Development Quality Performance and Risk Management, Pfizer
- ▶ **Patricia Leuchten**, Founder and CEO, The Avoca Group