Wednesday, March 21, 2018 | Main Conference Day Two

7:45 Registration and Continental Breakfast

8:30 **CHAIRPERSON'S OPENING AND RECAP OF PREVIOUS DAY**

Joanne Spallone, *Global Development Quality Audit Head,* **NOVARTIS**

8:45 **MEASURING CLINICAL RISK**

Outlining a Practical Approach for Identifying and Measuring Risk in Clinical Trial Operations

Denise Calaprice, Ph.D., *Senior Consultant,* **THE AVOCA GROUP**

- Understanding the purpose of a comprehensive risk measurement system
- Defining the different classes of metrics that should be used to assess and monitor risk in clinical trial operations
- Outlining a practical framework to support comprehensive consideration of the full pathway to each important clinical trial outcome and the nature of events that could put each at risk

9:30 **PANEL DISCUSSION: RISK MANGEMENT TOOLS**

PANEL DISCUSSION

Evaluating Various Systems, Tools and Processes That Have Proven Effective for Proactively Measuring, Tracking and Managing Clinical Risk

Panelists

Richard Azueta, Head, *GxP Audit,* **NOVARTIS**

Cheri Wilczek, *President,* **CLINAUDITS, LLC**

Additional Panelists TBD

- Sharing what's worked and what hasn't to measure, manage and track risk in clinical operations
  - -Leveraging the trial master file as a risk management tool
  - -Understanding how audits can be used to assess risk management
- Reviewing effective strategies for leveraging a quality management system to proactively identify risk

10:30 Networking Break

11:00 **TRANSCELERATE'S FREE RISK ASSESSMENT CATEGORIZATION TOOL (RACT)**

Leveraging RACT to Define, Categorize and Quantify Clinical Trial Risk

Karine Julien, *Executive Director, Quality Assurance Therapeutic Area Head, Primary Care,* **MERCK**

- Understanding RACT as a tool to standardize risk interpretation to reduce subjectivity, and improve overall risk management awareness in the industry
- Utilizing RACT to define the study Impact, Probability and Detectability (IPD) and completion status
- Evaluating how RACT is customizable and scalable to companies and studies of all sizes
- Visualizing the overall risk assessment of the study to allow for better control and collaboration to take action and mitigate

11:45 **PANEL DISCUSSION: TRAINING OPTIMIZATION**

PANEL DISCUSSION

Evaluating Effective Strategies to Optimize GCP Training and Mitigate Risk of Non-Compliance

Panelists Jennifer Clark, *Director, Quality Systems,* **FERRING PHARMACEUTICALS, INC.**

Cheryl McCarthy, RQAP-GCP, CQA, CBA, *Associate Director, R&D Quality and Compliance,* **BIOGEN**

Shari Zeldin, BS, CCRC, *Clinical Research Compliance Officer, Department of Medicine,* **UNIVERSITY OF WISCONSIN**

- Evaluating the effectiveness of traditional training methods and where it can be improved
- Understanding what types of training methods meet regulators' expectations
- Discussing what new kinds of training programs, methodologies and harmonized approaches have proven to be effective
- Measuring the effectiveness of training programs and how to demonstrate value and decreased risk

12:45 Lunch

1:45 **TESARO CASE STUDY: STANDARDIZING GxP SOPs**

CASY STUDY

Establishing a Foundation of Base Processes and Action Sequences That Are Consistent Across the Organization for Identification and Mitigation of Risk

Dan Greenwood, *Senior Director, Quality Assurance,* **TESARO**

- Recognizing the operational and compliance benefits of eliminating the variability in SOPs across GxP
- Examining the resulting consistent approach to auditing and vendor communication across the organization
- Understanding the procedural and language differences between GMP and GCP and how they were bridged
  - -Optimizing GCP operations by leveraging efficiencies from GMP practices
- Improving risk identification and mitigation with standardized procedures

2:30 **PANEL DISCUSSION: ESCALATION PLANS AND CLINICAL CAPAs**

PANEL DISCUSSION

Discussing Effective Procedures for Handling and Resolving Issues Once They've Been Identified

Panelists Teresa DeVincentis, *Senior Director, Clinical Quality Management,* **CELGENE**

Dawn Lundin, *Director, Quality Assurance,* **MERCK**

Doreen McGirl, *Director, Quality Assurance,* **CARDIOVASCULAR RESEARCH FOUNDATION**

- Defining the issue escalation plan, communication plan, and CAPA and understanding how they relate
- Establishing transparency and avoiding a blame culture to uncover any issues as early as possible
- Evaluating who should be involved in establishing and managing issue escalation plans and CAPAs
- Translating past experiences into action items that avoid recurrence

3:30 **CHAIRPERSON'S CONCLUDING REMARKS**

Joanne Spallone, *Global Development Quality Audit Head,* **NOVARTIS**

3:45 Close of Conference