Stay on the Pulse of Evolving Clinical Technology and Strategies to Enhance Clinical Trial Efficiencies

OCTOBER 23, 2018 • HILTON AT PENN’S LANDING • PHILADELPHIA, PA

Esteemed Conference Co-Chairs:

Ken Grice, eCOA Strategist, Bayer
Donna Mongiello, Vice President, Strategic Solutions, YPrime

BENCHMARKING CRITICAL INSIGHTS AND SOLUTIONS TO DRIVE eCOA STRATEGY:

- Understand areas of regulatory focus related to eCOA, BYOD, eICF integration and wearables
- Discuss approaches and operational strategies to drive eCOA development
- Leverage wearables and connected devices to enhance data collection and accuracy
- Examine key components for a successful eCOA translation process
- Address the value of integration between eCOA and IRT
- Identify processes and system considerations for eCOA data collection and management

PRACTICAL EXPERTISE AND INDUSTRY VIEWPOINTS FROM COMPANIES INCLUDING:

BAYER  YPRIME  SHIRE  ELI LILLY & CO  RWS LIFE SCIENCES  AMGEN  CLINICAL INK

HIGH QUALITY, INSPIRING AND INSIGHTFUL conference that pinpoints important topics in the field of eCOA. – HEOR Scientist, AstraZeneca

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CBI’s eCOA/ePRO 2018 stays on the pulse of the increasing utilization of mobile devices, sensors, wearables and other innovative technologies in clinical trial data collection. This interactive conference provides the opportunity for peer-to-peer benchmarking and in-depth sessions for actionable takeaways related to the use of technology to support clinical trials and high quality data collection.

WHO SHOULD ATTEND:

You will benefit from attending this event if you have responsibilities or involvement in the following areas:

- ePRO / eCOA
- Clinical Technology
- Clinical Operations
- Clinical Information
- Clinical Trial Management
- Clinical Development
- Data Management
- Business Technology
- Health Economics and Outcomes Research (HEOR)
- Clinical Innovation
- Data Sciences
- Informatics/Bioinformatics

The conference will also benefit consultants, technology vendors and companies providing services to the above audience.

EDUCATIONAL SPONSOR:

YPrime offers more than a decade of focused work with eClinical systems to expedite and improve the quality of patient management, clinical supplies, drug accountability and clinical data. Cloud-based interactive response technology (IRT) and electronic Clinical Outcome Assessment (eCOA) platforms enable greater speed, precision and integration in clinical trial management. Our data services tools help sponsors bring together fragmented clinical research data into contextual information they can act on. YPrime’s technology and service offerings enable sponsors to move faster and more efficiently to their next development milestone.

ADDITIONAL SPONSORS INCLUDE:

A Great Place to Meet Your Market!

Maximize your access to decision-makers and align your brand with the life sciences industry’s premier thought-leaders and industry innovators. CBI’s custom sponsorship programs are designed to support your organization's overall business development and marketing initiatives through meaningful prospect and customer interactions, brand assertion campaigns and content-rich thought-leadership opportunities. Capitalize on the life sciences community’s premier platform for peer-to-peer exchange, solution driven content and first-in-class networking opportunities. For more information on how to position your company as a sponsor or exhibitor, contact John Egan at 339-298-2205 or email john.egan@cbinet.com.
7:30  Conference Registration and Networking Breakfast

8:15  Conference Co-Chair’s Welcome and Opening Remarks

Ken Grice, eCOA Strategist, Bayer
Donna Mongiello, Vice President, Strategic Solutions, YPrime

8:30  Stay on the Pulse of Regulatory Oversight to Ensure Audit Readiness

• Evaluate the current landscape and areas of focus related to eCOA, BYOD, eICF integration and wearables
• Navigate guidelines around data change requests for eCOA data
• Gain learnings from trials that have been submitted utilizing BYOD

Jonathan Helfgott, Program Coordinator/Faculty, Regulatory Science and Food Safety Regulation, Johns Hopkins University

9:15  PANEL DISCUSSION
Approaches and Operational Strategies to Drive eCOA Development

• Considerations for eCOA vendor selection (cost, timeline, solution design)
• Define and monitor KPIs for eCOA and improved vendor performance
• Insight into lessons learned to maximize efficiencies and minimize cost
• Overcome operational challenges faced with studies utilizing eCOA including data transmission, missing data and patient error
• Determine the most efficient ways to capture data and what devices best suit the needs of the study

PANELISTS:
Aaron McCormick, Lead IRT and ePRO Operations Specialist, Shire
Janet Connolly-Giwa, eCOA Operations, Manager, Amgen

10:00  Networking and Refreshment Break

10:30  CASE STUDY
End-to-End Processes to Streamline Translation Management

• Understand the key components for a successful eCOA translation process
• Gain insight into models to centralize translations and gain cost and time efficiencies
• Understand best practices for enhancing the quality of deliverables
• Overcome challenges that can put a timely delivery at risk

Damaris Jusino, Manager, eCOA Operations, Eli Lilly & Co
Elizabeth McCullough, Linguistic Validation Services Manager, RWS Life Sciences

11:15  Configuration in ePRO – Making Design More Accessible and Delivering Better Results

• Agile vs. Waterfall — A new model in study project management
• Prototypes over documents in review and approval — Improving confidence and quality
• Collaboration in design for a better patient experience

Kyle Hogan, eClinical Solutions Director, Clinical Ink

12:00  Networking Luncheon

1:00  Leverage Wearables and Connected Devices to Enhance Data Collection and Accuracy

• Discuss the shift to patient-centric models and incorporating patient feedback
• Determine how to select a wearable device that will be appropriate based on need
• Identify the evidence needed about the validity of the device by regulators
• Develop standards and initiatives to implement approaches in trials

An INFORMATIVE AND ENGAGING conference that not only highlighted the many facets of the featured topic but also explored other pertinent industry related issues.

– LV Research Analyst, Corporate Translations
1:45  Practical Expertise of Running BYOD Trials
- Address risks and develop strategies to ensure compliance
- Execute strategies to overcome technical challenges, measurement equivalence and data security
- Discuss decision-making to determine which trial is right to pilot BYOD
- Develop key concepts to measure patient burden, perform instrument validation review and ensure patients are able to stay on protocol
- Anticipate what is to come for value and health in clinical trial technology

Willie Muehlhausen, Managing Director, Willie Muehlhausen Ltd, former Vice President, Head of Innovation, ICON plc

2:00  The Value of Integration Between eCOA and IRT
- Learn key considerations for when integration makes sense
- Recognize how eCOA and IRT data can drive and complement each other
- Learn how to stay ahead of the integration curve

Michael Hughes, Vice President, Operations and Development, YPrime

2:45  Networking and Refreshment Break

3:15  Processes and System Considerations for eCOA Data Collection and Management
- Implement best practices for user acceptance testing (UAT) of eCOA
- Design software programming to include logical branching, randomization and device-level calculations
- Identify key considerations to streamline data analysis and reporting
- Utilize predictive analytics and real-time reporting for real-time performance and risk metrics
- Provide ongoing training and communication of best practices to sites

4:00  Knowledge Exchange and Wrap-Up
This interactive session convenes all presenters and attendees to discuss best practices garnered from the conference as well as address unanswered questions to ensure participants return to the office with ready-to-implement strategies.

FACILITATORS:
- Ken Grice, eCOA Strategist, Bayer
- Donna Mongiello, Vice President, Strategic Solutions, YPrime

5:00  Close of Conference

Join Us for a Networking Wine and Cheese Reception at the Close of the Conference

HAVE A COLLEAGUE WORKING IN IRT?
TELL THEM ABOUT OUR CO-LOCATED EVENT!
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PHONE 339-298-2185
EMAIL michael.berube@cbinet.com

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Register by September 14, 2018 and SAVE $200.
Fee includes continental breakfast, lunch, wine and cheese reception, refreshments and conference documentation. Credit Card (Visa, MC, AMEX, Discover) or checks accepted. Please make checks in U.S. funds drawn on a U.S. bank payable to: CBI. (No personal checks accepted.) PLEASE NOTE: All advertised discounts are taken from the full, Standard Rate.

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Looking to bring your team? Contact Information Services to learn about potential group savings. Call 800-817-8601 or email cbireg@cbinet.com.

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SUBSTITUTION AND CANCELLATION:
Your registration may be transferred to a member of your organization up to 24 hours in advance of the conference. All cancellations received in writing on or before 14 days prior to the start date of the event will be refunded, less a $399 administrative charge. No refunds will be made after this date; however, the registration fee less the $399 administrative charge can be credited to another CBI conference if you register within 30 days from the date of this conference to an alternative CBI conference scheduled within the next six months. In case of conference cancellation, CBI’s liability is limited to refund of the conference registration fee only. Cancellation of a conference due to events beyond our control* are subject to a $399 administrative charge should you or a colleague be unable to attend the rescheduled date. CBI reserves the right to alter this program without prior notice. Please Note: Speakers and agenda are subject to change.

In the event of a speaker cancellation, every effort to find a suitable replacement will be made. The opinions of the conference faculty do not necessarily reflect those of the companies they represent or CBI.

*Events beyond our control include: severe weather conditions, natural and man-made disasters and any other similar events.

VENUE:
Hilton Philadelphia at Penn’s Landing
201 S. Christopher Columbus Boulevard
Philadelphia, PA 19106
Reservations: (800) 445-8667
Hotel Phone: (215) 521-6500

ACCOMMODATIONS:
To receive CBI’s special discounted hotel rate online or by phone, please go to:
• Online: www.cbinet.com/ecoa
• Phone reservations: (800) 445-8667 and mention CBI’s eCOA/ePRO

Book Now! The Hilton at Penn’s Landing is accepting reservations on a space and rate availability basis. Rooms are limited, so please book early. All travel arrangements subject to availability.

PLEASE NOTE: All hotel reservations for this conference should be booked directly with the hotel. CBI does not use Housing Bureaus and none are authorized to call on our behalf.

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