July 17-18, 2017
Sheraton Philadelphia University City Hotel // Philadelphia, PA

exl pharma 2017

Clinical Trial Protocol Optimization and Design Congress

Promote Collaboration and Understanding Between All Stakeholders in Protocol Development to Optimize Outcomes and Improve Patient Care

FEATURED SPEAKERS

Jim Kremidas
Executive Director, **ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS**

Sheri Kuss
Associate Director, Trial Optimization and Standards, **TEVA**

Richard Murray
Vice President and Deputy Chief Patient Officer, **MERCK**

Mary Westrick
Adjunct Faculty (Phase I Clinical Trials Specialty), **UNIVERSITY OF WISCONSIN, MADISON**

Kunal Sampat, MNA
Senior Manager, Clinical Programs, **ABBOTT VASCULAR**

Rosemarie Pincus, Ph.D.
Principal Medical Writing Scientist, Oncology Division, **JOHNSON & JOHNSON**

TOP 2017 SESSIONS

- Design Protocols to Embrace Reality: A Phase I Perspective
- **CASE STUDY:** Consider the Site Perspective on Protocols to Build Strategic Relationships that Promote Clinical Success
- Write Quality Protocols to Focus on Streamlining, Clarity and Consistency Within the Study Documents
- **ROUNDTABLE DISCUSSION:** Examine the Potential Outcomes of Building a Consistent Protocol Template
- Integrate Wearable Technology with Protocols to Improve Clinical Data Gathering and Patient Centricity
- Review How Protocol Design Is Flawed and Affecting Clinical Research
- **PROVIDER PANEL:** Gain the Site and Patient Perspective
- Explore the Four P's Surrounding Patient Centricity

KEY OBJECTIVES

- **Improve** clinical research operations with optimized protocols that incorporate stakeholder perspectives
- **Discuss** new techniques to optimize trial protocols and recognize time and physiological constraints
- **Understand** the importance of intelligent protocol design and how it translates to improved clinical trial success and patient care
- **Share** techniques and best practices with other pharmaceutical industry professionals to implement a consistent and qualified industry standard
- **Incorporate** site input early in the protocol writing stage to increase collaboration across the study and expedite the protocol process

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Dear Colleague,

Clinical protocols are the framework for a clinical trial. From the amount of samples to take from a patient to the time frame and schedule for the study, protocols ensure every detail, incident or outcome is planned for and recorded. Over the past few years, protocols have been under tremendous scrutiny for their feasibility and lack of insight and flexibility regarding patient limits and site resources. This absence of collaboration causes major delays in study start-up timelines. A contributing factor to these missteps is the use of non-practicing physicians from pharmaceutical companies, many of whom have never seen a patient outside their residency, to write and form these complex documents with limited knowledge of how long a procedure takes or its effect on a patient's health. The document then goes through scientific review, which should catch the missteps mentioned before, but instead causes procedure inflation, adding unneeded and costly steps to the process. The issues with the current status quo go on, but the **2017 Trial Protocol Optimization and Design Congress** will foster a space for professionals to improve the industry and its processes.

Protocol optimization has made a resurgence as a major component of the pharmaceutical industry. Sponsors, sites and CROs are noticing how inflated protocols have become, how protocol amendments are costing companies millions, and how protocols are unrealistic for patients to participate in and practitioners to operate. The summit explores how protocol optimization will improve inclusion/exclusion criteria, reduce the time each procedure takes and help life science professionals better understand what is physiologically possible to accomplish with a patient. Protocol optimization will improve patient care and outcomes, site performance and recruitment, and the bottom line for drug development.

The 2017 Clinical Trial Protocol Optimization Congress will bring decision-makers from sites, pharma, CROs and other stakeholders in the protocol writing process together to discuss how the industry should change their policies and procedures. With topics on inclusion/exclusion, advisory boards, training for protocol writers and patient feasibility, the congress will foster a space the industry can build upon in order to improve all aspects of clinical trial protocol optimization and design.

I look forward to welcoming you to Philadelphia in July!

Sincerely,

Tyler Lobo

Tyler Lobo
Conference Production Director
ExL Events, a Division of Questex, LLC

WHO SHOULD ATTEND

This conference is designed for professionals from clinical research sites and pharmaceutical, medical device and biotechnology companies with responsibilities in the following areas:

- **Protocol Optimization/Design/ Planning**
- **Trial Optimization/Design**
- **Protocol Management**
- **Protocol Writing**
- **Clinical Operations**
- **Clinical Research**
- **Regulatory Affairs**
- **R&D Operations**
- **Quality Assurance**
- **Patient Centricity**
- **Process Optimization**
- **Site Relations**
- **Trial/Clinical Compliance**
- **Process Improvement**
- **Clinical Safety**
- **Site/Trial Feasibility**

This event may also be of interest to:

- **Clinical/Academic Research Organizations**
- **Protocol Writing Software Providers**
- **Clinical Trial Management Software Companies**
- **Clinical Trial Optimization Services**
- **Protocol Consultants**

VENUE

Sheraton Philadelphia University City Hotel

3549 Chestnut St., Philadelphia, PA 19104

To make reservations please call 1-888-627-7070 and request the negotiated rate for ExL's Real-World Evidence and 2017 Trial Protocol Optimization Design Congress Meetings. You may also make reservations online at http://bit.ly/2ooGqhE. The group rate is available until June 30, 2017. Please book your room early as rooms available at this rate are limited.

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Agenda // Day One – Monday, July 17, 2017

8:00 Continental Breakfast and Registration

9:00 Chairperson's Opening Remarks

PROTOCOL PAIN POINTS

9:15 **Review How Protocol Design Is Flawed and Affecting Clinical Research**

- Hear examples of current flaws and issues with clinical trial protocols and how they affect the industry and the patient
- Understand why we need to construct processes that promote quality, speed and equity in trial start-up activities and protocol implementation
- Discuss how optimizing protocol design processes could provide intelligent solutions to issues surrounding research operations and patient care

Richard Murray, *Vice President and Deputy Chief Patient Officer,* **MERCK**

10:00 **Apply Quality by Design Techniques During Protocol Development to Decrease Complexity and Risk**

- Review the ramifications of overly complex clinical trial protocols, including their impact on compliance, risks, costs, amendments and enrollment
- Highlight Quality by Design (QbD) principles and tools to decrease risk and unnecessary procedures within a protocol
- Identify risk management and protocol optimization techniques to reduce costly amendments and inefficient trials

Sheri Kuss, *Associate Director, Trial Optimization and Standards,* **TEVA**

10:45 Networking Break

11:15 **Discuss the Disconnect Between Protocol Design and the Capabilities of All Stakeholders**

- Generate a two-way conversation between stakeholders in the clinical trial industry to better respond to feedback on time tables, operational feasibility and physiological constraints
- Understand how protocols should be written and designed to be applicable to the practitioners and patients conducting the research
- Accept and apply feedback from other stakeholders to the design process and integrate that feedback in a cohesive and positive manner

Jim Kremidas, *Executive Director,* **ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS**

12:00 Luncheon

PARTNERSHIPS IN PATIENT CENTRICITY

1:00 **Engage the Patient Perspective in Clinical Trial Protocol Design to Ensure Patient Centricity and Healthy Outcomes**

- Recognize where the trial ends and the patient begins — work to view patients as people, not subjects
- Collaborate to ensure protocols are feasible and equitable for those being tested and those doing the testing
- Incorporate the patient in every point of design to promote recruitment, outcomes and adherence

William Smith, M.D., FACC, *President,* **NEW ORLEANS CENTER FOR CLINICIAL RESEARCH**

1:45 **Improve Inclusion and Exclusion Criteria to Safeguard Successful Patient Recruitment and Retention**

- Evaluate the impact of "nice-to-have" inclusion and exclusion criteria on clinical trial enrollment
- Ask the right questions to the right people to prevent repeated and expensive protocol amendments
- Collaborate cross-functionally with all stakeholders to determine if delayed enrollment is worth the risk

Kunal Sampat, MNA, *Senior Manager, Clinical Programs,* **ABBOTT VASCULAR**

2:30 Networking Break

3:00 **PROVIDER PANEL: Gain the Site and Patient Perspective**

- Assess implementing an initiative to understand patient and site partnerships at a clinical level and how they apply those insights to clinical trials
- Consider the effect a program involving these perspectives might have on clinical trial quality and patient health outcomes
- Gauge the relationship health between pharmaceutical companies and their sites and how an initiative would improve and build a bond between them

Jeff Kingsley, *Chief Executive Officer,* **IACT HEALTH**

William Smith, M.D., FACC, *President,* **NEW ORLEANS CENTER FOR CLINICIAL RESEARCH**

Mary Westrick, *Adjunct Faculty (Phase I Clinical Trials Specialty),* **UNIVERSITY OF WISCONSIN, MADISON**

Ashish Atreja, *Chief Technology Engagement and Innovation Officer,* **ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI**

4:00 **Leverage Patient Insight for Protocol Optimization and Develop Patient-Focused Communications**

- Work alongside the patient to understand roadblocks in literature and develop more reader-friendly documents
- Ensure the patient is the center of the trial starting with the literature provided to them at recruitment until the end of the trial, keeping them informed with dignity and respect
- Capitalize on patient insight to improve recruitment activities that envelope a more diverse and educated population

Madeline Geday, *Associate Director, Clinical Research, Global Trial Optimization,* **MERCK**

4:45 **Explore the Four P's Surrounding Patient Centricity**

- Discuss why and how issues in patient enrollment continue to plague the industry
- Identify and address the problems in enrollment by using innovative and customized techniques
- Clarify how metrics and figures to predict protocol success shouldn't be solely relied on for recruitment
- Focus on the psychological factor behind each individual person during recruitment to improve practices and results

Kate Vila, *Founder & Business Development Manager,* **OPULENT GROUP, LLC**

5:30 Day One Concludes

Agenda // Day Two – Tuesday, July 18, 2017

8:00 Continental Breakfast

8:45 Chairperson's Recap of Day One

TRIAL PROTOCOL DESIGN AND OPTIMIZATION

9:00 **Design Protocols to Embrace Reality: A Phase I Perspective**

- Focus efforts to use realistic and pragmatic criteria when recruiting and qualifying subjects
- Conduct a "reality check" on your protocol design to identify pitfalls or obstacles
- Consider a less-than-perfect population to better understand the possible effects of a drug on a real-world subject

Mary Westrick, *Adjunct Faculty (Phase I Clinical Trials Specialty),* **UNIVERSITY OF WISCONSIN, MADISON**

9:45 **Realize the Benefits of Reliable Adherence Data Through the Introduction of Electronic Compliance Monitors Early in Trial Design**

- Discuss the widely accepted premise that patients aren't always compliant with medication instructions and dosing
- Discover how medication non-adherence injects error into clinical trials, leading to inaccurate results affecting protocol optimization
- Hear how having valuable electronic adherence data can be quantified and used as a source of statistical power in your trial design
- Look at the relationship between electronic adherence monitors and your ROI

Allan Wilson, M.D., Ph.D., *President,* **INFORMATION MEDIARY CORPORATION**

10:30 Networking Break

11:00 **CASE STUDY: Consider the Site Perspective on Protocols to Build Strategic Relationships that Promote Clinical Success**

- Incorporate the site perspective to improve protocol writing and procedures that create realistic processes and trial frameworks
- Use feedback from sites not just as a requirement, but as a resource to optimize the trial by eliminating expensive, needless and even invasive procedures
- Resolve areas of contempt with site partners that often cause tension, which can create roadblocks and pitfalls for study start-up

Jeff Kingsley, *Chief Executive Officer,* **IACT HEALTH**

11:45 **Gauge the Impact of Trial Data Collection and Analysis on the Sponsor and Patients**

- Consider the significant impact on the patient and sponsor if data is not collected and/or analyzed properly
- Share the current and future state-of-the-art methods for data collection and analysis via case examples
- Hear recommendations for a clinical trial professional's day-to-day work during data collection and analysis

Patrick Hu, *Senior Safety Physician,* **ASTRAZENECA**

12:30 Lunch

INDUSTRYWIDE SOLUTIONS AND CONSISTENCY

1:30 **Write Quality Protocols to Focus on Streamlining, Clarity and Consistency Within the Study Documents**

- Discuss techniques for organizing time and event schedules for ease of layout and understanding
- Keep a clear "line of sight" to minimize the number of study assessments and to align objectives to endpoints of study procedures
- Add flexibility to a study protocol by use of adaptive design to prevent controllable amendments
- Learn checks and balances that promote the quality of a protocol or amendment

Rosemarie Pincus, Ph.D., *Principal Medical Writing Scientist, Oncology Division,* **JOHNSON & JOHNSON**

2:15 Networking Break

2:45 **Integrate Wearable Technology with Protocols to Improve Clinical Data Gathering and Patient Centricity**

- Introduce the many new devices, techniques and software programs that have come to market for clinical research
- Understand the amount of data wearables can deliver and how to analyze it efficiently
- Overcome obstacles to the adoption of wearable technology presented by patients, sites and other members of the industry

Ashish Atreja, *Chief Technology Engagement and Innovation Officer,* **ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI**

3:30 **ROUNDTABLE DISCUSSION: Examine the Potential Outcomes of Building a Consistent Protocol Template**

- Shape the way the industry will build a consistent protocol template that encompasses all essential elements of the protocol while maintaining clinical integrity
- Adhere to the fundamental tenets of change management to navigate the evolution of protocol development
- Conceptualize the positive or negative outcomes that a consistent protocol template can provide and determine the depth of changes that should be made

If you are interested in participating in this session, please contact Tyler Lobo at tlobo@exlevents.com.

4:15 Chairperson's Closing Remarks

4:30 Conference Concludes

"I've had the privilege of participating in and presenting at several ExL Pharma conferences in the US and Europe. This company arranges some of the best-organized and informative industry conferences in my experience."

–Senior Director, Oncology Field Operations, **SANOFI-AVENTIS**

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web: http://pmaconference.com/
Mail: POB 2303 Falls Church Va 22042

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Conference	$1,795
STANDARD PRICING – *Register After June 2, 2017*	
Conference	$1,995
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