eXL events

October 19-20, 2017 / Sheraton Philadelphia University City / Philadelphia, PA

4th CLINICAL TRIALS PHASE I & PHASE IIA SUMMIT

Advance early-phase clinical trials through increased safety standards and improved strategic partnerships

SAFETY

- Ensure New Best Practice Standards When Monitoring Patient Safety
- Identify, Prepare for, and Recruit Special Populations
- Integrate Adaptive Trial Design and Dual-Purpose Biomarkers of Efficacy to Enhance Safety in Early-Phase Clinical Trials

STRATEGIC PARTNERSHIPS

- Develop Best Practices to Ensure Communication Standards Are Met
- Overseeing Protocol Uncertainties
- Managing the Negotiation Cycle
- Outsourcing Early-Phase Clinical Studies

NEW TECHNOLOGIES AND ADVANCEMENTS

- Virtual Clinical Trials Place in Early-Phase Development
- Practical Aspects of Integrating Wearable Technology to Advance Studies and Improve Patient Interaction and Retention
- Utilize the Appropriate Software to Optimize Early-Phase Studies

PROCESS IMPROVEMENT

- Design Operating Models for Early Clinical Trials
- Improve Early Development Oncology Studies
- Identify Early-Phase Signals of Safety to Reduce the Risks of Drug Development

Sponsors:

Clinical Trials of Texas, Inc. CTT 15 Years of Excellence

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HIGH POINT CLINICAL TRIALS CENTER

inSeption GROUP

FEATURED SPEAKERS

Mary Westrick,
Adjunct Faculty,
UNIVERSITY OF WISCONSIN, MADISON

Barry Ticho,
Head of Development CVMD,
MODERNA THERAPEUTICS

Rachael Easton,
Senior Director, Translational Medicine and Clinical Pharmacology,
SANOFI

Chad Swanson,
Director, Neuroscience Clinical Development,
EISAI, INC.

Samuel Volchenboum,
Director, Center for Research Informatics,
UNIVERSITY OF CHICAGO GRAHAM SCHOOL

Dr. Margarita Nunez,
Medical Director and Principal Investigator,
HIGH POINT CLINICAL TRIALS CENTER

Marcus Stavchansky,
Director, Pharmacy Services,
COVANCE

Dear Colleague,

The data obtained from Phase I first-in-human studies through Phase II proof-of-concept and dose range-finding studies are vital to effectively designing future studies. The strategic optimization of these early phase clinical trials can ensure the success of a drug's trial execution and regulatory approval.

As early-phase clinical research is designed to demonstrate safety and efficacy as well as pinpoint the right population, effectiveness, and dosage, it is important for biotech and pharmaceutical companies to not only make sure these trials are designed properly but also monitor them closely. It is essential for sponsors to properly design their trial as well as communicate with sites and CROs to ensure regulations are met, and standards are upheld. Strategic partnering with the right organizations is the surefire way to ensure a successful trial, and the best way to set you up for future success. A properly designed trial means a meticulous evaluation that clarifies risk and benefits; a poor design could make an inadequate drug appear good.

The implementation of new technology and forward-thinking innovations has the potential to revolutionize the industry. The **4th Clinical Trials Phase I & Phase IIA Summit** is the premier early-phase clinical trial event to learn how to advance trials through increased safety standards and improved strategic partnerships, and the best place to hear from industry professionals who are changing the world for the better.

VENUE

Sheraton Philadelphia University City Hotel
3549 Chestnut Street
Philadelphia, PA 19104

To make reservations, please **call 1-888-627-7071** and request the negotiated rate for **ExL's October Meetings**. You may also make reservations online using the following weblink: **http://bit.ly/2nJ4T5s**. The group rate is available until **September 27, 2017**. Please book your room early, as rooms available at this rate are limited.

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WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, biotechnology, clinical sites, and CROs with responsibilities in the following areas:

- Early-Phase Research/Development
- Clinical Research/Operations/ Optimization/Outsourcing/Affairs
- Pharmacology/Pharmacokinetics/ Pharmacodynamics
- Pharmacovigilance
- Translational Science/Medicine
- Site Design
- Biostatistics/Biometrics
- Pharmacometrics
- Clinical Informatics
- Clinical Data Management/Statistics
- Protocol/Feasibility Development
- Clinical Innovation
- Regulatory Affairs/Compliance
- Medical Research/Affairs
- Patient Recruitment/Engagement
- Compound Development
- Chief Science Officers/Senior Scientists
- Biologics
- Trial Design Management
- Drug Safety
- Formulation
- Product Development
- Clinical Investigators
- Clinical Site Coordinators (CRCs)/ Monitors (CRAs)

This conference is also of interest to:

- Clinical Research Organizations
- Clinical/Quality Risk Consultants
- Medical Informatics Professionals
- Business Development Professionals
- Patient Engagement and Retention Services
- Clinical Technology and Data Management Solution Providers
- Functional Service Providers

8:30 Registration and Continental Breakfast

9:15 Chairperson's Opening Remarks

PROCESS IMPROVEMENT

9:30 **Design Operating Models for Early Clinical Trials**

- Identify and overcome barriers of a fast and efficient clinical trial
- Vet partners, contract negotiations, CRO monitoring, and audits
- Design your trial: A good design means a meticulous evaluation that clarifies risks and benefits

Mary Westrick, *Adjunct Faculty,* **UNIVERSITY OF WISCONSIN-MADISON**

10:15 **Challenges and Successes With Outsourcing Early-Phase Clinical Studies to the Right Strategic Partner**

- Strategically align with the right partners to meet your organization's goals
- Develop the best plan to utilize your company's resources and capabilities
- Review of sponsors' obligations and best practices for outsourced clinical trials

Kristian Hubbard, *Outsourcing Manager, Clinical Science and Operations Department,* **BRISTOL-MYERS SQUIBB**

Susan Lubin, *Outsourcing Manager,* **BRISTOL-MYERS SQUIBB**

11:00 Networking Break

11:30 **Design a Bayesian Adaptive Phase II Proof-of-Concept Trial for the Treatment of Alzheimer's Disease**

- Recent Phase 3 failures in Alzheimer's disease studies can be partially attributed to a lack of sufficient Phase 2 proof-of-concept data, suggesting that a novel approach may be necessary
- BAN2401-G000-201 is a Bayesian adaptive Phase 2 proof-of-concept study that was designed to help mitigate the risk of Phase 3 failure through the most efficient use of ongoing study data
- Present work highlights the important role that simulations play in developing the essential design components of this Bayesian adaptive study

Chad Swanson, *Director, Clinical Neuroscience,* **EISAI**

12:15 **Identify, Prepare for, and Recruit Special Populations**

- New FDA guidelines, changing early-phase studies in special populations
- Improve community outreach and involvement in special population studies
- Implement best practices for proof-of-concept studies to satisfy sponsor needs and FDA regulations

Dr. Margarita Nunez, *Medical Director and Principal Investigator,* **HIGH POINT CLINICAL TRIALS CENTER**

1:00 Luncheon

2:15 **Perfect Data Management to Enhance Speed, Quality, and Safety**

- Accelerate your Phase I and Phase IIA trials with the right data management system in place
- Manage multiple sites to maintain data integrity across various platforms
- Streamline study design by implementing best practice standards

3:00 **Develop a New Chemical Entity Using Phase I cGMP Manufacturing**

- Lower the cost of drug manufacturing to vastly reduce your overall expenditures
- Progress through your trial timeline more quickly and efficiently to eliminate frustration during your first-in-human studies
- Yield benefits in quality, safety, and cost when using a cGMP pharmacy for drug development

Marcus Stavchansky, Pharm.D., *Director, Pharmacy Services,* **COVANCE**

3:45 Networking Break

4:15 PANEL **Practical Aspects of Integrating Wearable Technology to Advance Studies and Improve Patient Interaction and Retention**

- Improve patient retention through better monitoring and communication practices
- Address user complications: Storage capacity, system updates, data security
- Assess the viability of working with different operating systems
- Effects of patients upgrading, changing, or losing a device mid-trial

Moderator:
Samuel Volchenboum, *Director, Center for Research Informatics,* **UNIVERSITY OF CHICAGO GRAHAM SCHOOL**

5:00 Conference Day One Ends

Friday, October 20, 2017

Day Two

8:30 Continental Breakfast

9:15 Chairperson's Recap of Day One

STRATEGIC PARTNERSHIPS

9:30 **Challenges and Opportunities for Early Development in Asia**

- Adjust to the changing regulatory environment in China: The implications and opportunities for early development
- Enable simultaneous global development through best practices and strategic partnerships

Rachael Easton, *Senior Director, Translational Medicine and Clinical Pharmacology,* **SANOFI**

10:15 **Integration of Adaptive Trial Design and Dual-Purpose Biomarkers of Efficacy to Enhance Safety in Early-Phase Clinical Trials**

CASE STUDY

- Thinking outside the box and off-target: Biomarkers of off-target pathways may enhance safety and proof-of-concept
- Adaptive trial design considerations: Delaying proof-of-concept testing methods until biological activity has been detected in ascending dose studies may contain both costs and risk

Clayton Dehn, MS, *Senior Vice President Early SVC and Strategic Development,* **CLINICAL TRIALS OF TEXAS, INC.**

11:00 Networking Break

11:30 **Monitor Patient Safety and Data Collection for Early-Phase Therapeutic Interventional Oncology Studies**

- Standardize data collection and storage to increase efficiency and optimize interventional studies
- Develop clinical biomarker strategy and execution for Immuno-Oncology studies
- Define acceptable and safe approval endpoints

12:15 **Create Operational Standards That Allow Flexibility in Order to Effectively Adapt to Protocol Uncertainties**

- Set processes in place to ensure quick, effective handling of any issues that may arise
- Develop your protocol in line with ICH GCP guidelines
- Design clinical trial protocol to ensure integrity of data and safety of patients

Lucy Xu, *Associate Director, Clinical Biomarker Reseearch,* **EISAI**

1:00 Luncheon

SAFETY AND REGULATIONS

2:15 **Explore New Approaches to Reduce Risk and Ensure Safety in First-in-Human Early Clinical Development**

PANEL

- Manage timelines and costs while addressing safety concerns with partners
- Review past clinical trials with major adverse events and discuss what alternate measures could have been taken to increase patient safety
- Evaluate various trial designs to determine best practices

Howard E. Greenberg, *Medical Safety Officer and Operational Chair, FIHC,* **JANSSEN;** *Adjunct Faculty,* **THOMAS JEFFERSON UNIVERSITY**

3:00 **Identify Early-Phase Signals of Safety to Reduce Risks Involved with Drug Development**

PANEL

- Determine if there are unreasonable risks with limited data in early-stage clinical studies
- Assess adverse events and offer solutions for first-in-human studies to maximize patient safety
- Address partner expectations to manage time lines and cost while highlighting safety

Panelists:

Barry Ticho, *Head of Development CVMD,* **MODERNA THERAPEUTICS**

3:45 **Look to the Future of Clinical Trials: Virtual Clinical Trials' Place in Early-Phase Development**

- Patient interaction: Recruitment, enrollment, engagement, and counseling of patients all become simplified and easier to monitor
- Reduce risk: Remote monitoring devices could be accessed in real time by trial investigators thus removing the reporting of adverse effects from the patients' responsibilities
- Combat patient concerns: Security of sending personal data remotely, and a lack of in-person support staff
- Balance the initial investment of sophisticated technology with the long-term benefit of reduced overhead costs

4:30 Conference Concludes

Registration Fees for Attending ExL's 4th Clinical Trials Phase I & Phase IIA Summit

EARLY BIRD PRICING—*Register by Friday, September 8, 2017*	**$1,895**
STANDARD PRICING—*Register After Friday, September 8, 2017*	**$2,095**
ONSITE PRICING	**$2,195**

Group Discount Program

Save 25% per person when registering four

For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

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Offers may not be combined. Early Bird rates do not apply. To find out more about how you can take advantage of these group discounts, contact our offices at (201) 871-0474.

Media Partners

Testimonials

"Good presentations, interesting information and fantastic networking."

—Clinical Operations, **ACTELION**

"This was one of the most informative and worthwhile conferences I attended in the last few years. It truly delivered the objectives of the conference in regards to early-phase trials and such a great networking venue."

—Director, Early-Phase Clinical Operations, **SANOFI**

"Great sessions and speakers on implementation and the future use of technology in clinical trials."

—Associate Director, **NOVARTIS**

"Great speakers with relevant and important topics discussed."

—R&D Outsourcing Manager, **LEO PHARMA**

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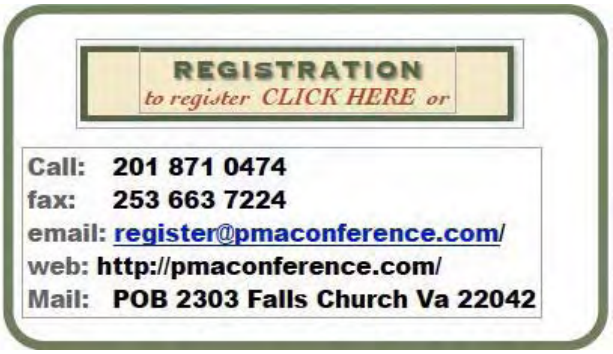

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