MARCH 22–23, 2018 | WYNDHAM PHILADELPHIA HISTORIC DISTRICT | PHILADELPHIA, PA

Adaptive Clinical Trials SYMPOSIUM

Analyze Statistics, Data Management, and Operations to Improve Clinical Performance

FEATURED SPEAKERS

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

Ramses Sadek, *Professor of Biostatistics and Head of Cancer Clinical Trial Biostatistics Unit,* **AUGUSTA UNIVERSITY**

Feng Liu, *Manager Statistics,* **GLAXOSMITHKLINE**

Vladimir Dragalin, Ph.D., *Vice President, Scientific Fellow and Head of Quantitative Sciences Consultancy Group,* **JANSSEN R&D, USA**

Alex Sverdlov, *Director, Statistical Sciences,* **NOVARTIS**

Divya Chadha Manek, *Business Development Manager,* **NATIONAL INSTITUTE FOR HEALTH RESEARCH**

Mingxiu Hu, *Senior Vice President, Head of Data Science and R&D Systems,* **NEKTAR THERAPEUTICS**

Balazs Flink, *Head of Clinical Trial Analytics, Business Insights and Analytics,* **BRISTOL-MYERS SQUIBB**

Peter Zhang, *Head of Biostatistics,* **OTSUKA**

Inna Perevozskaya, *Senior Director and U.S. Team Lead Statistical Innovation Group,* **GLAXOSMITHKLINE**

SPECIAL FOCUS

INTERIM ANALYSIS AND ADAPTIVE DESIGN EVOLUTION

- Write Protocols Knowing That Changes Are Likely to Occur
- Combat the Challenges of a Potentially Heterogeneous Population
- Improve Data Quality and Statistical Efficacy

ANALYZE DATA

- Use Statistical Analysis to Make Modifications That Optimize Study Execution
- Beyond KPIs: What Are You Missing?
- Advancements in Data Collection For Neurological Diseases

STAKEHOLDER OVERVIEW

- Develop Protocol, Optimal Study Design, Data Analysis, Randomization, and a Statistical Analysis Plan
- Coordinate With Key Stakeholders and Regulatory Agencies to Ensure Study Protocols Are Met
- Discover the Best Practices to Share Data With Partners to Improve Clinical Performance

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Adaptive Clinical Trials SYMPOSIUM

An average clinical trial can cost $60–80 million. Adaptive design allows a sponsor to modify multiple parts of a trial without incurring additional costs. An adaptive design can stipulate that data be collected at various intervals, allowing the opportunity for modification of one or more detailed aspects of the study based on analysis of this data. It is believed that this advantage will allow a trial to more efficiently demonstrate the effects of a drug. ExL Events' **Adaptive Clinical Trials Symposium** brings together senior-level executives from pharmaceutical and biotechnology companies to examine the best practices when taking advantage of adaptive design through case studies, thought-provoking presentations, and interactive panel discussions.

Adaptive clinical trial design allows for modifications to the trial after it begins without damaging the integrity of the study. An adaptive design allows for a more proficient use of capital and resources through shorter time frames and fewer patients. Using adaptive design sponsor organizations can allocate resources more efficiently without lowering standards and therefore are able to accelerate the clinical development process.

During interim analysis, trial organizers review and analyze data before all the "needed" data is collected. This pivotal point where an adaptive trial differs from a traditional design allows a sponsor to change their protocol and make the necessary adjustments, without compromising the trial or starting over — ultimately saving time and resources.

Join us to ensure you have all your questions answered. Gain key insights behind developing, using, and implementing adaptive design in order to proactively boost clinical research and effectively lower costs. You will leave the Adaptive Clinical Trials Symposium analyzing statistics, data, and operations through interim analysis for more efficient clinical trials.

WHO SHOULD ATTEND

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

- Biostatistics
- Clinical Trial Design
- Medical Research
- Clinical Operations/Research
- Clinical Supplies
- Data Management
- Patient Recruitment
- Project Management
- Regulatory Affairs/Operations
- Drug Development
- Clinical Development

This conference is also of interest to:

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

VENUE INFORMATION

Wyndham Philadelphia Historic District

400 Arch Street
Philadelphia, PA 19106

To make reservations, please call 1-877-999-3223 and request the negotiated rate for **ExL's March Meetings**. You may also make reservations online using the following weblink: http://bit.ly/2z68WhH. The group rate is available until **February 28, 2018**. Please book your room early, as rooms available at this rate are limited.

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AGENDA DAY ONE // THURSDAY, MARCH 22

8:00 Continental Breakfast and Registration

9:00 **Chairperson's Opening Remarks**

9:15 **The Platform Trial — An Efficient Approach to Clinical Development of Novel Compounds**

- Identify effective treatments and match patients to the therapies they are most likely to benefit from
- Achieve optimal efficiency by using common control, multiple arms, response-adaptive randomization, improved power, and precision through the use of totality of data
- Establish a regulatory opportunity for transformational innovation in medical research

Vlad Dragalin, Ph.D., *Vice President, Scientific Fellow and Head of Quantitative Sciences Consultancy Group,* **JANSSEN R&D, USA**

10:00 **Improve Patient Enrollment Outcomes through Real-Time Corrections During the Recruitment Process**

- Recognize the Analytical Overview Between Site Selection and Recruitment Methods
- Understand how to Enhance Patient Recruitment Efficiently with Real-Time Screening Alert
- Distinguish Strategies and Tactics Designed to Maintain Patients Enrolled in Clinical Trials

Amer Alghabban, *Managing Director, GxP Expert and Trainer,* **ALNYLAM PHARMACEUTICALS**

10:45 Networking Break

11:15 **Advancements in Data Collection for Neurological Diseases**

- Assess various digital devices to identify the best options for predicting clinical outcomes
- Pitfalls of current data collection procedures and how wearable technology will solve these problems
- Process improvement for identifying and selecting the best strategic partners

Alex Sverdlov, *Director, Statistical Scientist,* **NOVARTIS**

12:00 **Accelerated Approval at Interim Analysis and a Long-Term Endpoint for Full Approval at Final Analysis With Sample Size Adaptation Based on the Long-Term Endpoint**

- Analyze endpoints to increase the speed of decision-making
- Select treatment arms based on surrogate endpoints to accelerate a study and confirm analysis
- Utilize the appropriate statistical methods for the use of surrogates in interim analysis decisions

Mingxiu Hu, *Senior Vice President, Head of Data Science and R&D Systems,* **NEKTAR THERAPEUTICS**

12:45 Luncheon

1:45 **In-Depth Look at the Bayesian Method for Adaptive Clinical Trial Design for the Treatment of Alzheimer's Disease**

- Distinguish the mechanics and physical use of this novel design to understand the probability of success
- Utilize multiple interim analyses in a Phase Two proof-of-concept study to mitigate risk of Phase Three failure
- Determine the challenges and opportunities when implementing a 12-month endpoint in an 18-month study

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

2:30 **Accelerating Adaptive Clinical Trials via Virtual Collaboration**

- Explore the increased need for rapid and in-depth communication within adaptive trials
- Learn about modern virtual communication tools that are redefining trial operations
- Understand how new social technologies are supporting the broader clinical trial spectrum

Lance Hill, *CEO,* **WITHIN3**

3:15 Networking Break

3:45 **Recruit Patients With Inclusion/Exclusion Criteria That Are Less Strict Than Usual to Allow for Adaptive Design**

- Real-world examples of Interim Analysis and Adaptive Design evolution
- Write protocols knowing that changes are likely to take place
- Combat the challenges of a potentially heterogeneous population and the ramifications for data quality and statistical efficacy

Ramses Sadek, *Professor of Biostatistics and Head of Cancer Clinical Trial Biostatistics Unit,* **AUGUSTA UNIVERSITY**

4:30 **Plan an Adaptive Trial Based on New FDA Guidance**

- Design a trial based on a specific genetic feature (biomarker) rather than the location where the tumor originated
- Keep up with the latest changes to the standards of care and anticipate future shifts to the competitive landscape while trials are in progress

5:15 Day One Ends

"Very rich knowledge sharing amongst audience and panelists."
***—Director,* BRISTOL-MYERS SQUIBB**

"Broadened my knowledge through the experiences of others."
***—Associate Director,* MERCK**

AGENDA DAY TWO // FRIDAY, MARCH 23

8:00 Continental Breakfast

8:45 **Chairperson's Recap of Day One**

9:00 **Discover How Adaptive Design Influences Operational Analytics**

- Determine the differences between what we should do and what we could do in oncology drug development
- Throw the old paradigms and concepts created by outdated efficacy endpoints utilized by the FDA and recreate them from scratch
- Identify best practices when dealing with the ever-changing landscape of oncology studies

Balazs Flink, *Head of Clinical Trial Analytics, Business Insights and Analytics,* **BRISTOL-MYERS SQUIBB**

9:45 **Presented by Veristat**

10:30 **Utilize dose escalation in Bayesian design to determine the efficacy and toxicity of a drug**

- Modify one or more detailed aspects of the study based on analysis at various intervals
- Demonstrate the effects of a trial drug more efficiently
- Follow key endpoints: Bioavailability, dose-finding and dose-response, cognitive efficacy, and potential additions to treatment

Inna Perevozskaya, *Senior Director and U.S. Team Lead Statistical Innovation Group,* **GLAXOSMITHKLINE**
Yuehui Wu, *Director Statistics,* **GLAXOSMITHKLINE**

11:15 Networking Break

11:45 **Adaptive Trial Design: Delivering the Unicorn of Clinical Trials in the UK**

- Understand how adaptive trial designs are enabling better patient outcomes
- Discuss the benefits of a platform where all stakeholders engage at a country level to make innovations work
- Demonstrate examples of setting up adaptive design in a single-study platform

Divya Chadha Manek, *Business Development Manager,* **NATIONAL INSTITUTE FOR HEALTH RESEARCH**

12:30 **Use Statistical Analysis to Make Modifications That Optimize Study Execution Without Affecting Validity and Integrity**

- Accumulate clinical trial data about a study for adaptive design
- Make clinical trials more efficient through shorter time frames and fewer patients
- Accelerate the clinical development process by allocating resources to maximize productivity without lowering scientific and regulatory standards

Peter Zhang, *Head of Biostatistics,* **OTSUKA PHARMACEUTICALS**

1:15 Luncheon

2:15 **Implement an Adaptive Approach Early in the Clinical Program to Improve Decision-Making and Yield Cost Savings**

- Reduce developmental timelines through well-founded recruitment and enrollment strategies
- Apply extensive pre-planning and strategy in protocol development
- Initiate a plan for patient recruitment before site selection to avoid costly delays

Feng Liu, *Manager Statistics,* **GLAXOSMITHKLINE**

3:00 **Design and Implementation Differences of Simple and Complex Adaptive Trials**

- Optimize clinical development plans through adaptive design
- Analyze the different procedures of a simple adaptive design and a complex design
- Understand when to utilize simplicity over complexity with adaptive trial design

4:15 **Chairperson's Closing Remarks**

4:30 Conference Concludes

"Learn how to run an interim analysis efficiently and using the most appropriate technique."
—Research and Development Statistician, GLAXOSMITHKLINE

"Looking forward to sharing with my stats team and getting their perspective on methods."
—Senior Manager Clincial Systems, **EDWARD LIFESCIENCES**

"Gave 'food for thought' on how to avoid missing data at interim data points."
—Director, Clinical Research, Clinical Quality Management Lead, **MERCK**

"Good to hear the perspective from a different stakeholder and one who often gets overlooked."
—Associate Director, Medical and Safety Services, **GEORGE CLINICAL**

REGISTRATION INFORMATION

Registration Fees for Attending ExL's Adaptive Clinical Trials Symposium

EARLY BIRD PRICING	STANDARD PRICING	ONSITE PRICING
Register by Friday, February 9, 2018	*Register After Friday, February 9, 2018*	
$1,895	**$2,095**	**$2,195**

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