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

SPONSORS

VERISTAT

Within3
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.

*ExL Events is not affiliated with exhibition Housing Management (EHM)/Exhibitors Housing Services (EHS) or any third-party booking agencies, housing bureaus, or travel and events companies. ExL Events is affiliated with event company Questex, LLC. In the event that an outside party contacts you for any type of hotel or travel arrangements, please disregard these solicitations, and kindly email us at info@exlevents.com. ExL has not authorized these companies to contact you and we do not verify the legitimacy of the services or rates offered. Please book your guest rooms through ExL’s reserved guest room block using the details provided.
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00</td>
<td>Continental Breakfast and Registration</td>
</tr>
<tr>
<td>9:00</td>
<td>Chairperson’s Opening Remarks</td>
</tr>
<tr>
<td>9:15</td>
<td><strong>The Platform Trial — An Efficient Approach to Clinical Development of Novel Compounds</strong></td>
</tr>
<tr>
<td>10:00</td>
<td>Improve Patient Enrollment Outcomes through Real-Time Corrections During the Recruitment Process</td>
</tr>
<tr>
<td>11:15</td>
<td><strong>Advancements in Data Collection for Neurological Diseases</strong></td>
</tr>
<tr>
<td>12:00</td>
<td><strong>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</strong></td>
</tr>
<tr>
<td>1:45</td>
<td><strong>In-Depth Look at the Bayesian Method for Adaptive Clinical Trial Design for the Treatment of Alzheimer’s Disease</strong></td>
</tr>
<tr>
<td>2:30</td>
<td><strong>Accelerating Adaptive Clinical Trials via Virtual Collaboration</strong></td>
</tr>
<tr>
<td>3:45</td>
<td><strong>Recruit Patients With Inclusion/Exclusion Criteria That Are Less Strict Than Usual to Allow for Adaptive Design</strong></td>
</tr>
<tr>
<td>4:30</td>
<td><strong>Plan an Adaptive Trial Based on New FDA Guidance</strong></td>
</tr>
<tr>
<td>5:15</td>
<td>Day One Ends</td>
</tr>
</tbody>
</table>

**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 Pervoezskaya, 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 Maneck, 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

“Gave ‘food for thought’ on how to avoid missing data at interim data points.”
—Director, Clinical Research, Clinical Quality Management Lead, MERCK

“Looking forward to sharing with my stats team and getting their perspective on methods.”
—Senior Manager Clinical Systems, EDWARD LIFESCIENCES

“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**

**TERMS AND CONDITIONS:** By registering for an ExL Events ("ExL") event, you agree to the following set of terms and conditions listed below:

**REGISTRATION FEE:** The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

**PAYMENT:** Please make checks payable to "PMA" and write C1001 on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offer and must be paid in full at the time of order. Parties must be employed by the same organization and register simultaneously to realize group discount pricing options.

**SUBSTITUTION CHARGES:** There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of the conference.

**CANCELLATION AND REFUND POLICY:** If you cancel your registration for an upcoming ExL event, the following policies apply, derived from the Start Date of the event:

- **Four weeks or more:** A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
- **Less than four weeks:** A voucher to another ExL event valid for 12 months from the voucher issue date.
- **Five days or less:** A voucher (minus a $395 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.

To receive a refund or voucher, please email cancel@exlevents.com or fax your request to 888-221-6750.

**CREDIT VOUCHERS:** Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of registration, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees’ behalf, the credit voucher will no longer be valid.

---

### Registration Fees for Attending ExL’s Adaptive Clinical Trials Symposium

<table>
<thead>
<tr>
<th></th>
<th>Early Bird Pricing</th>
<th>Standard Pricing</th>
<th>Onsite Pricing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Register by</td>
<td>Friday, February 9, 2018</td>
<td>Register After Friday, February 9, 2018</td>
<td></td>
</tr>
<tr>
<td>Price</td>
<td>$1,895</td>
<td>$2,095</td>
<td>$2,195</td>
</tr>
</tbody>
</table>

**GROUP DISCOUNT PROGRAM**

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

- **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.

- **SAVE 15% PER PERSON WHEN REGISTERING THREE**
  - Can only send three? You can still save 15% off of every registration.

---

**MEDIA PARTNERS**

**EARLY BIRD PRICING**

<table>
<thead>
<tr>
<th>Media Partner</th>
<th>Website</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ExL Events</td>
<td>exlevents.com</td>
<td>Adaptive Clinical Trials Symposium.</td>
</tr>
</tbody>
</table>

**STANDARD PRICING**

<table>
<thead>
<tr>
<th>Media Partner</th>
<th>Website</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacopeia</td>
<td>pharmaphore.com</td>
<td>Pharmacy innovation and strategy.</td>
</tr>
<tr>
<td>PM360</td>
<td>pm360.com</td>
<td>Medical Product Marketing.</td>
</tr>
</tbody>
</table>

**ONSITE PRICING**

<table>
<thead>
<tr>
<th>Media Partner</th>
<th>Website</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ExL Events</td>
<td>exlevents.com</td>
<td>Adaptive Clinical Trials Symposium.</td>
</tr>
</tbody>
</table>

---

**TERMS AND CONDITIONS:** By registering for an ExL event, you agree to the following set of terms and conditions listed below:

**REGISTRATION FEE:** The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

**PAYMENT:** Please make checks payable to "PMA" and write C1001 on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offer and must be paid in full at the time of order. Parties must be employed by the same organization and register simultaneously to realize group discount pricing options.

**CANCELLATION AND REFUND POLICY:** If you cancel your registration for an upcoming ExL event, the following policies apply, derived from the Start Date of the event:

- **Four weeks or more:** A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
- **Less than four weeks:** A voucher to another ExL event valid for 12 months from the voucher issue date.
- **Five days or less:** A voucher (minus a $395 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.

To receive a refund or voucher, please email cancel@exlevents.com or fax your request to 888-221-6750.

**CREDIT VOUCHERS:** Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of registration, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees’ behalf, the credit voucher will no longer be valid.

---

**EARLY BIRD PRICING**

<table>
<thead>
<tr>
<th>Media Partner</th>
<th>Website</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ExL Events</td>
<td>exlevents.com</td>
<td>Adaptive Clinical Trials Symposium.</td>
</tr>
</tbody>
</table>

**STANDARD PRICING**

<table>
<thead>
<tr>
<th>Media Partner</th>
<th>Website</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacopeia</td>
<td>pharmaphore.com</td>
<td>Pharmacy innovation and strategy.</td>
</tr>
<tr>
<td>PM360</td>
<td>pm360.com</td>
<td>Medical Product Marketing.</td>
</tr>
</tbody>
</table>

---

**EARLY BIRD PRICING**

<table>
<thead>
<tr>
<th>Media Partner</th>
<th>Website</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ExL Events</td>
<td>exlevents.com</td>
<td>Adaptive Clinical Trials Symposium.</td>
</tr>
</tbody>
</table>

---

ExL Events does not and is not obligated to provide a credit voucher to registered attendee(s) who do not attend the event they registered for unless written notice of intent to cancel is received and confirmed prior to the commencement of the event.

**SUBSTITUTION CHARGES:** There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of the conference.

ExL Events reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or any other expenses incurred by registrants.

ExL Events’ liability is limited to the conference registration fee in the event of a cancellation and does not include changes in program date, content, speakers and/or venue.

*The opinions of ExL’s conference speakers do not necessarily reflect those of the companies they represent, nor ExL Events.*

Please Note: Speakers and agenda are subject to change without notice. In the event of a speaker cancellation, significant effort to find a suitable replacement will be made. The content in ExL slide presentations, including news, data, advertisements and other information, is provided by ExL’s designated speakers and is designed for informational purposes for its attendees. It is NOT INTENDED for purposes of copywriting or redistribution to other outlets without the express written permission of ExL’s designated speakers. Neither ExL nor its content providers and/or speakers shall be liable for any errors, inaccuracies or delays in content, or for any actions taken in reliance thereon. ExL EVENTS EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, AS TO THE ACCURACY OF ANY CONTENT PROVIDED, OR AS TO THE FITNESS OF THE INFORMATION FOR ANY PURPOSE. Although ExL makes reasonable efforts to obtain reliable content from third parties, ExL does not guarantee the accuracy of, or endorse the views or opinions given by any third-party content provider. ExL presentations may point to other websites that may be of interest to you; however ExL does not endorse or take responsibility for the content on such other sites.