Decrease Cost and Increase Efficiency in Early Phase Clinical Trials While Addressing Challenges, Biomarker Techniques and Compound Development Strategies

October 15 - 16, 2014 / Hyatt at the Bellevue / Philadelphia, PA

TOP REASONS TO ATTEND:

1. Increase Phase I/IIA clinical trial efficiency by implementing an adaptive dosing structure that cuts time and cost

2. Optimize biomarker creation and utilization by implementing a biomarker strategy and analyzing utility for early decision-making

3. Learn the definition of BTD and explore what data is sufficient to bestow Breakthrough Therapy Designation status

4. Hear case studies from innovation leaders in Pfizer, Merck, MedImmune, Abbvie, AstraZeneca and Seattle Genetics

5. Learn from translational medicine professionals and compound/product development leaders as they discuss effective strategies and collaborate on innovative approaches to develop novel treatments

TO REGISTER Call 866-207-6528 or visit www.exlpharma.com/Phase1
There’s a pill for everything, at least, that is how it seems. Each year billions of dollars are funneled to develop new drugs and therapies before they are put on the market. Unsurprisingly, the vast majority of these costs are for clinical trial and regulatory expenses, but then question becomes “how can we decrease cost?”

The early phases of clinical trials are often the most expensive part of a trial because protocol has not yet been determined. Additionally this trial-and-error area of compound and product development is inefficient and this is reflected in the overall price tag. To decrease the cost of phase I and phase IIA clinical trials, we must utilize a playbook of strategies to decrease the study timeline, increase innovation and optimize efficiency. However, following through with these goals is easier said than done.

The main areas of Phase I and Phase IIA clinical trials include early challenges, translational medicine and compound development, innovation, efficiency, breakthrough therapy designation and patient recruitment and retention. Early challenges include optimizing novel-novel mechanisms and reactions to increase identification and demonstrate therapeutic effect in later proof of concept studies. Complexities arise within systems when it is necessary to create and implement unique biomarkers as part of this process. Another challenge occurs when attempting to increase innovation and efficiency within Phase I and Phase IIA clinical trials, while remaining compliant with strict FDA safety and regulatory requirements. Overall, the entire team involved in early phase clinical trials must utilize strategies and tactics from different clinical trial areas of focus and adapt them to their own protocol development if they intend to save time and money without cutting corners on future endeavors.

It now falls into the hands of industry professionals to develop strategies and tools that create an adaptable, efficient and enduring model of Phase I and Phase IIA clinical trial protocol processes so corporations large and small can continue to develop innovative life saving treatments for the global population.

At the Clinical Trials Phase I and Phase IIA Summit you will be able to learn from your colleagues on how to overcome challenges and increase efficiency within you clinical trial protocols. Through 15 plenary sessions, nine case studies and one panel session, this premier event will act as a playbook and provide you with proven strategies to enhance your organization.

We look forward to welcoming you to Philadelphia, Pennsylvania in October!

Sincerely,

Brendan Weiss
Conference Production Director

WHO SHOULD ATTEND

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

- Clinical Operations/ Program/ Research Management
- Clinical Data Management
- Research Coordination
- Research Scientist
- Drug Development
- Clinical Site Management
- Clinical Planning and Performance
- Medical Research
- Early Phase Patient Recruitment
- Translational Science/Medicine
- Compound Development
- Medical Development
- Biologics
- Clinical Informatics/ Pharmacovigilance
- Clinical Development Statistics/ Pharmacology
- Clinical Regulatory Affairs/ Compliance
- Clinical Outsourcing/ Procurement
- Trial Design Management
- Drug Safety
- Product Development

“VERY GOOD EXAMPLES PROVIDED. GREAT EXPLANATIONS TO QUESTIONS RAISED!”
– Associate Director, Pharmaceutical Sciences, TAKEDA

“AN EXCELLENT EVENT WITH VERY FOCUSED VIEWS OF NEW TECHNOLOGIES”
– Senior CMC Team Leader, ALCON LABORATORIES

VENUE

Hyatt at the Bellevue
200 South Broad Street, Philadelphia, PA 19102

Discover the true grandeur, unrivaled style, and service at our iconic downtown Philadelphia hotel. Situated on the famous Avenue of the Arts, Hyatt at The Bellevue blends old-world architecture with modern amenities. The city is yours to discover from the Hyatt at The Bellevue. From the historic Liberty Bell and Independence Hall to the Museum of Art and Eagles games at Lincoln Financial Field, you’ll find a wealth of attractions close to our Center City Philadelphia hotel. Head to Reading Terminal Market to explore the nation’s oldest continually operating farmer’s market and sample the original Philly Cheese Steak at Pat’s or the Bellevue’s own Rick’s. Wander through Rittenhouse Row for premier shopping, entertainment, and people watching. No matter your interests – whether indoors or out, cultural or athletic – you are sure to find plenty to keep you going from morning till night.

Room Reservations: If you require overnight accommodations, please contact the hotel to book your room. ExL Pharma has reserved a block of rooms at a discounted rate for conference participants. We encourage conference participants to make reservations by September 23, 2014 in order to receive the discounted rate. Please make your reservation early as rooms available at this rate are limited.

To make reservations guests can call 1-866-421-1442 and request the negotiated rate for ‘ExL’s October Meetings.’

TO REGISTER
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**A VERY WELL-ORGANIZED EVENT!**

– Scientist, DMPK, LEXICON PHARMACEUTICALS
5 Ways to Register

Mail: ExL Events, Inc.
494 8th Ave, Fourth Floor
New York, NY 10001

Phone: 866-207-6528
Fax: 888-221-6750
Email: registration@exlpharma.com
Online: www.exlpharma.com/Phase1

Registration Fees

**Early Bird Pricing  until September 12, 2014**
Registration Fee: $1,895

**Standard Pricing  after September 12, 2014**
Registration Fee: $2,095

**Onsite Pricing**
Registration Fee: $2,195

Group Discount Programs

Offers cannot be combined, early bird rates do not apply. To find out more on how you can take advantage of these group discounts, call 866-207-6528.

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 4 at one time).

Save 15% per person when registering three
Can only send three? You can still save 15% off of each registration.

Cancellation Policy

If you need to cancel your registration for an upcoming ExL conference, please note the following policies derived from the Start Date of the event:

- Four weeks or more: A full refund (minus $295 processing fee), or a voucher to another ExL event valid for 18 months from the voucher issue date.
- Four weeks or less: A voucher to another ExL event valid for 18 months from the voucher issue date. If you cancel at any time after receiving the conference documentation, the voucher will be $395 less.
- To receive a refund or voucher, please fax your request to 888-221-6750 or call 212-400-6240.

ExL Pharma reserves the right to cancel any conference if deemed necessary and will not be responsible for airfare, hotel, or any other costs incurred by registrants. ExL Pharma’s liability is limited to the conference registration fee in the event of a cancellation and/or speaker or discussion leader?

QUESTIONS? COMMENTS?

Do you have a question or comments that you would like to be addressed at this event? Would you like to get involved as a speaker or discussion leader? Please email Conference Production Director, Brendan Weiss at BWeiss@exlpharma.com

Do you want to spread the word about your organization’s solutions and services to potential clients who attend this event? Take advantage of the opportunity to exhibit, present an educational session, host a networking event, or distribute promotional items to attendees. ExL works closely to customize a package that suits all of your needs.

To learn more about these opportunities, contact, Andrew Ferguson, Business Development Manager 917-258-5150 or aferguson@exlpharma.com

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By registering for an ExL Events, Inc. (“ExL Pharma”) 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.
- The opinions of this faculty do not necessarily reflect those of the companies they represent or ExL events, Inc.

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New York, NY 10001

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Online: www.exlpharma.com/Phase1

☐ Yes! Register me for the conference only!

Name: ____________________________ Title: ____________________________

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CONFERENCE CODE: C533MM

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- Fax: 888-221-6750
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CLINICAL TRIALS

PHASE I & PHASE IIA

Decrease Cost and Increase Efficiency in Early Phase Clinical Trials While Addressing Challenges, Biomarker Techniques and Compound Development Strategies

October 15 - 16, 2014 / Hyatt at the Bellevue / Philadelphia, PA

SPEAKERS INCLUDE:

- MAUREEN HO, MS, Associate Director, Clinical Research Operations Center, MERCK
- KEN CHANG, Clinical Assay Development Lead, MERRCK CLINICAL BIOMARKER AND DIAGNOSTICS LAB
- NAUIRA V. BOER, Associate Director, Clinical Research Operations Center, MERCK
- LAWRENCE LESKO, Former Director of the Office of Clinical Pharmacology in the Center for Drug Evaluation and Research, FDA & current Professor of Pharmacos and Director of Center for Pharmacometrics and Systems Pharmacology, University of Florida College of Pharmacy
- ALESSANDRA TOSOLIN, Associate Director in Clinical Development Execution Organization—Clinical Oncology, MERCK SHARP & DOHME
- SID ROYCHOWDHURY, Compound Development Team Leader, JANSSEN
- ERIKA ZAVOD, Director and Operational Lead for Immunology & Head of Procedures GDO, TEVA PHARMACEUTICALS

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