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:

KEN CHANG
Clinical Assay Development Lead
MERCK CLINICAL BIOMARKER AND DIAGNOSTICS LAB

MAUREEN HO
Senior Scientist, Early Stage Clinical Development Specialist
MERCK

LAWRENCE LESKO
Former Director of the Office of Clinical Pharmacology in the Center for Drug Evaluation and Research FDA & current Professor of Pharmaceutics and Director of Center for Pharmacometrics and Systems Pharmacology, University of Florida College of Pharmacy

DAVID MITCHELL
Director and Global Regulatory Lead on Immunology, Neuroscience and Oncology, AbbVie

SID ROYCHOUDHURY
Compound Development Team Leader, JANSSEN

ERIKA ZAVOD
Director and Operational Lead for Immunology & Head of Procedures GCO, TEVA PHARMACEUTICALS

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

CONFERENCE CHAIRED BY:

SAMUEL BLACKMAN
Executive Director of Clinical Development, SEATTLE GENETICS

JAMIE OLIVER
Chief Science Officer, ACCELOVANCE

SPONSOR:
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,

Kristen Consalvo
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.’
AGENDA | Wednesday October 15, 2014

8:00 REGISTRATION OPENS & CONTINENTAL BREAKFAST

9:00 CO-CHAIRPERSON’S OPENING REMARKS
Samuel Blackman, MD, PhD, Executive Director of Clinical Development, SEATTLE GENETICS
Jamie Oliver, PharmD, Chief Science Officer, ACCELOVANCE

1:45 ADAPTIVE DESIGN IN PROOF OF CONCEPT STUDIES TO INCREASE EFFICACY, DECREASE TIME AND DECREASE OVERALL COST
- Use of an adaptive design for Proof of Concept studies to decrease the timeline between First-in-Human dosing to go/no-go in one year
- Optimize efficiency by increasing flexibility in dosage selection and by enrolling a small number of patients in the minimum number of panels to accelerate the phase II/IIA timeline
- Assess the advantages of an adaptive design for both enrollment and dosage selection in facilitating rapid decision making prior to substantial investments in time and money
Maureen Ho, MS, Early Clinical Scientist, Early Stage Development, MERCK

2:30 NETWORKING AND REFRESHMENT BREAK

3:00 CLINICAL FEASIBILITY AND IMPLEMENTATION OF A BIOMARKER ENRICHMENT STRATEGY IN EARLY PHASE CLINICAL TRIALS
- Pre-clinical versus clinical needs in biomarker enrichment strategies
- Strategic approaches to indentify biomarker targets for clinical trials
- Developing a biomarker enrichment strategy within the regulatory requirements
- Best practices to handle operational challenges and increase clinical feasibility by implementing a biomarker enrichment strategy
Alessandra Tosolini, Senior Scientist in Clinical Oncology, MERCK SHARP & DOHME

3:45 GLOBAL REGULATORY BEST PRACTICES FOR SIMULTANEOUS DEVELOPMENT AND APPROVAL OF THERAPEUTICS AND COMPANION DIAGNOSTICS (CDX)
- Global definitions of CDxs and the multiple types
- Understand global regulations, regulatory guidance and required/recommended submissions
- Best practices for CDx development for early clinical trials
- Case study examples and lessons learned from the approved CDxs
David Mitchell, MS, Director and Global Regulatory Lead in Oncology, ABBVIE

4:30 COMPOUND DEVELOPMENT STRATEGIES TO OPTIMIZE SUCCESS IN CLINICAL DEVELOPMENT
- Address key reasons why clinical trials underperform:
  - Safety, Pharmacokinetics, Pharmacodynamics, Target Engagement and Proof of Activity/Mechanism
  - Mechanistic Heterogeneity in patient populations
- Discuss the value in demonstrating target entanglement and proof of activity/mechanism in early clinical trials
- Analyze the biological factors in a variety of patient profiles via Phase 0 trials to explore the relevance of MoA under investigation
- Debate the merits of a singular target versus a combinatory target to increase success in proof of concept
Siddhartha Roychoudhury, PhD, Compound Development Team Leader, JANSSEN R&D

5:15 CONCLUSION OF DAY ONE

9:15 UTILIZE ANALYTICAL TECHNOLOGY TO EVALUATE MULTIPLE CONFIGURATIONS OF A SMALL MOLECULE TO INCREASE THE FEASIBILITY OF A DRUG IN CLINICAL TRIALS
- Simulate multiple configurations of a small molecule using "computational chemistry" to asses protein folding and ligand binding
- Explore the success rate of small molecules as they utilize pathways to partition the cellular membrane
- Utilize analytical statistics to quantitatively validate experimental results to predict and increase probable clinical trial success
- Eliminate possible pitfalls in early optimization studies and decrease the potential failure rate before heavily investing in clinical operations
Patrick Grinaway, Computational Chemistry Research Scientist, CORNELL UNIVERSITY

10:00 OPTIMIZE NOVEL/NOVEL MECHANISMS AND REACTION COMBINATIONS IN PHASE 1
- Utilize the lessons from the successes and failures in the monotherapy application of targeted therapeutics in oncology to increase the probability of success in novel/novel combinations in phase I
- Address the "Combination Problem" by implementing new strategies for combination prioritization
- Develop methods for accelerating phase I and Proof of Concept studies using novel clinical trial designs
Samuel Blackman, MD, PhD, Executive Director of Clinical Development, SEATTLE GENETICS

10:45 NETWORKING AND REFRESHMENT BREAK

11:15 EXPLORE THE GENETIC PROFILES OF A DISEASE
- Analyze the genetic profile of a disease to identify potential biomarkers and targets
- Tailor clinical trials to fit disease patient profiles
- Benefits and disadvantages of focused clinical trials on prospective patients and overall success

12:00 LUNCHEON

1:00 BEST PRACTICES AND METHODS TO SELECT STARTING DOSAGE FOR FIRST-IN-HUMAN STUDIES
- Analysis of animal to human model conversion techniques to develop starting dosage in human trials
- Methodologies to identify the number of doses to show a positive therapeutic effect
- Optimizing the right dosage and number of participants to prove proper dosage without accruing additional costs and extraneous data
Sohayla Rostami, Clinical Scientist in Oncology Clinical Development, MEDIMMUNE
AGENDA | Thursday October 16, 2014

8:00 REGISTRATION OPENS & CONTINENTAL BREAKFAST

8:45 CO-CHAIRPERSON’S OPENING REMARKS

Samuel Blackman, MD, PhD, Executive Director of Clinical Development, SEATTLE GENETICS
Jamie Oliver, PharmD, Chief Science Officer, ACCELOVANCE

9:00 CREATE A COLLABORATIVE ENVIRONMENT BETWEEN THE DRUG DEVELOPMENT TEAM MEMBERS

• Listen to effective strategies that guide early clinical trials through the drug development pipeline
• Learn from industry leaders as they collaborate on new, innovative approaches to develop novel treatments

Samuel Blackman, MD, PhD, Executive Director of Clinical Development, SEATTLE GENETICS
Siddhartha Roychoudhury, PhD, Compound Development Team Leader, JANSSEN R&D

INNOVATION

10:00 APPLICATION OF PHARMACOGENOMICS DURING PHASE I CLINICAL TRIALS

• Explore the inter-individual variability drug response to different medications and discuss the potential reasons for these different responses including environmental, physiological and pathological factors
• Address how genetic differences can affect patient response to different medications
• Learn the pharmacogenomic aspects of CYP enzymes and transporters in early drug development
• Understand how pharmacogenomics can be applied in optimizing different aspects of drug development

Timi Edeki, MD, PhD, Senior Director of Global Clinical Research, ASTRazenECA

10:45 NETWORKING AND REFRESHMENT BREAK

11:15 BEST PRACTICES FOR EARLY DECISION-MAKING THROUGH ANALYSIS OF BIOMARKER UTILITY IN DRUG DEVELOPMENT

• Mitigate risk of late-stage development failure with strategies to identify safety or efficacy signals as early as possible
• Generate best practices for developing clinical safety and efficacy biomarkers
• Address risks and benefits of biomarker utility in drug development with specific case studies

Norah Shire, PhD, MPH, Translational Medicine – Infectious Diseases, MEDImmUNE

12:00 ADDRESS ISSUES AND LESSONS LEARNED IN ONCOLOGY CLINICAL TRIALS WITH AN EMPHASIS ON BIOMARKERS AND DIAGNOSTICS

• Proven strategies for clinical development
• Implement best practices from multiple clinical trial protocol experiences
• Share challenges with special considerations for internal and outsourced biomarker assay development and validation to the assay transfer to outside vendors
• Impact the efficiency and success of early phase clinical trials

Ken Chang, PhD, Clinical Assay Development and Outsourcing Lead, MERCK CLINICAL BIOMARKER AND DIAGNOSTICS

LAB

12:45 LUNCHEON

1:45 SEAMLESS DEVELOPMENT OF PHASE I TO PHASE II IN CLINICAL TRIALS

• Strategize phase II development to streamline phase III go/no-go decisions
• Assess the risks and benefits in terms of timeline and cost implications for clinical operations
• Explore the therapeutic areas where this process may work and may not work
• Hear the operational considerations in early phases that effect later phase development
• Discuss the aspects of country and site selection that may benefit from seamless strategies
• Implementation of communication and documentation strategies internally

Erika Zavod, MS, Director and Operational Lead for Immunology, Head of Procedures GCO, TEVA PHARMACEUTICALS

BREAKTHROUGH THERAPY DESIGNATION

2:30 THE DEFINITION OF BREAKTHROUGH (BTD) AND REQUIREMENTS FOR ACHIEVING SUCCESS

• Clear definition of Breakthrough Therapy Designation
• Requirements and qualifications for seeking BTD approval
• Leveraging the benefits of BTD versus the perceived value
• Reasons for denial of BTD
• Reflections on BTD approvals

Lawrence Lesko, Former Director of the Office of Clinical Pharmacology in the Center for Drug Evaluation and Research, FDA & current Professor of Pharmaceutics and Director of Center for Pharmacometrics and Systems Pharmacology, UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY

3:15 NETWORKING AND REFRESHMENT BREAK

PATIENT RECRUITMENT AND RETENTION

3:45 SUCCESSFUL APPROACHES TO PATIENT RECRUITMENT AND RETENTION FOR EARLY PHASE CLINICAL TRIALS

• Current clinical trial patients discuss their perspectives and insights
• Utilize technological advancements and social media tools to target potential patients
• Simplify trial design to decrease patient drop outs and encourage a patient’s want to participate
• Reduce data to minimize patient amendment requirements
• Adaptive trial design to enroll small numbers of the “right” patients

Melissa Drexel, MS, Senior Clinical Scientist, Early Stage Development, MERCK

4:15 SUMMIT CONCLUDES

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– Scientist, DMPK, LEXICON PHARMACEUTICALS
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