



West Coast Clinical Trials, LLC

Invites you to attend

WCCT Symposium May 18, 2010 San Francisco: Accelerating Early Clinical Development

FREE Registration - Limited to First 50 Registrants

May 18, 2010, Tuesday
Hilton Garden Inn San Mateo
2000 Bridgepointe Circle,
San Mateo, California, USA 94404

Accelerating Early Clinical Development

Moderator: Kenneth Kim, MD

- 8:30 - 9:00 Continental Breakfast and Registration
- 9:00 - 9:30 Laying the Groundwork for a Successful Early Development Program (Discussion on designing preclinical programs consistent with current regulatory trends)
Paul Frohna, MD, PhD, PharmD, ProFibrix
- 9:30 - 10:00 *Fast and Smart Drug Development*
Richard Shames, MD, Merck & Co.
- 10:00 – 10:20 Coffee Break
- 10:20 - 10:45 Integrating Japan and Asia into Global Development
Richard Lowenthal, Principal, Pacific-Link
- 10:45 - 11:15 Advanced ECG Analyses in Early Clinical Development
Anthony Fossa, PhD, iCardiac
- 11:15- 11:45 Panel Discussion: Question and Answer Session

Program Overview

Laying the Groundwork for a Successful Early Development Program

Learning as much as possible about your investigational agent during preclinical development is essential for designing a smart clinical development plan, which typically requires the identification of biomarkers for safety, activity, and efficacy that translate to the clinic. A recent industry trend for combining pharmacology and safety measures in early preclinical studies will also be discussed. Finally, the applicability of recent FDA guidances, like the Critical Path Initiative and Exploratory INDs, for your program also need to be considered before designing the most efficient and effective early development program for your company.

Fast and Smart Drug Development

Successful drug development is not only about accelerating timelines but implementing effective design strategies. Many drugs fail in late stage development because of insufficient proof of concept and inadequate dose finding in early stage development. Effective strategies that target the relevant patient population, use appropriate biomarkers and surrogate endpoints, utilize adaptive design and characterize the full dose range of activity can help to reduce risk and maximize the probability of accelerating the “winners” and eliminating the “losers”.

Integrating Japan and Asia into Global Development

The complexity, time and cost of drug and biologic development has lead companies to focus more on global development and streamlining the approach to bridging drug development across regions. This talk will focus on approaches to integrating Japan and Korea into the global development process and accelerating time to market in Asia.

Advanced ECG Analyses in Early Clinical Development

Highly automated ECG analysis technologies have recently been validated in studies with the FDA. With this technology tens of thousands of cardiac cycles can be utilized to implement newer beat-to-beat methodologies of analysis for the same costs as tradition 12-sec ECGs strips without using error prone correction factors. These technologies can help differentiate QT interval effects to the ICH E14 standard and improve decision making at earlier stages in development where fewer subjects are needed.



Bridging Science For Better Health

Presenter Profiles:

Paul Frohna, MD, PhD, PharmD, ProFibrix

Paul A. Frohna, MD, PhD, PharmD is currently Chief Medical Officer at ProFibrix, Inc. Dr. Frohna has extensive experience designing preclinical, clinical and regulatory strategies, and has designed and conducted more than 20 Phase I-III clinical trials in the U.S., Canada and Europe. He has previously held senior positions in clinical pharmacology and clinical development at Fibrogen Inc., CV Therapeutics, and Genentech.

Richard Shames, MD, Merck & Co.

Dr. Shames is Senior Director of Clinical Research and Early Biologics Lead (Immunology) at Merck Research Labs in Palo Alto where he manages the early stage development of novel biologics candidates in autoimmune/ inflammatory diseases. Prior to joining Merck, Dr. Shames served as Therapeutic Area Head of Immunology at Facet Biotech (formerly PDL BioPharma), and Assistant Professor of Pediatrics (Allergy/ Immunology) at UCSF and Stanford. He is Board Certified in Pediatrics and Allergy/ Immunology.

Richard Lowenthal, Principal, Pacific-Link

Richard Lowenthal MSc MBA is President and Founder of Pacific-Link Regulatory Consulting, a transpacific company supporting companies developing advanced biologics. Mr. Lowenthal was formerly at the FDA, and worked for various large and small companies, including J&J PRD, AnGes, Somerset, Maxim and Cadence. Mr. Lowenthal has held positions as Global Project Leader in CNS Development at J&J and as Vice President of Regulatory Affairs and Quality Assurance at several pharmaceutical and biotechnology companies. His current focus is in supporting biologics development for Japanese and Korean companies conducting research in the United States and for Western companies interested in development activities in Japan.

Anthony Fossa, PhD, iCardiac

Dr. Fossa is the Vice President of Cardiovascular Safety at iCardiac Technologies. Previous to iCardiac, Anthony was a Research Fellow at Pfizer for over 20 years where he was responsible for all preclinical cardiovascular assessment related to Safety Pharmacology in early development. During that time he developed new methodologies, such as beat-to-beat and ECG restitution analyses which are now available for clinical usage through iCardiac. Dr. Fossa is a co-author on the FDA white paper for QT assessment recommendations of drugs that affect heart rate and autonomic state.

REGISTER NOW

Email: RSVP@wcct.com

Fax: (714) 252-0789

Voice Message: (714)252-0713

Registration is FREE.

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Name: _____

Company: _____

Address: _____

Phone: _____

Email: _____

Tuesday, May 18, 2010

Event Location:

Hilton Garden Inn San Mateo
2000 Bridgepointe Circle,
San Mateo, California, USA 94404
Tel: 1-650-522-9000 - Fax: 1-650-522-9099

Complimentary Parking and Continental Breakfast

West Coast Clinical Trials (WCCT) is a privately held 120-bed clinic located in Southern California that specializes in Phase I-IV clinical studies. WCCT has a unique focus on Ethno-bridging studies along with extensive experience with healthy volunteer and specialty trials (allergy, asthma, infectious disease, pediatric, renal and vaccines). For more information, visit our website at www.wcct.com.