



**Second Annual Conference**  
**Data Driven Decisions: From Preclinical to Post-Marketing**  
**April 19<sup>th</sup> – April 21<sup>st</sup>, 2012 ★ Hotel Lalit Ashok ★ Bengaluru, India**



**CONFERENCE SUMMARY**

IASCT is pleased to announce its 2nd Annual Conference. The theme of this year's event is **Data Driven Decisions: From Preclinical to Post-Marketing**.

The conference will feature talks on a diverse selection of topics in drug discovery, development and marketing, where statistics plays a key role. There will be four half-day workshops on April 19, followed by two days of presentations & discussions.

Over 20 eminent speakers and 200 delegates from across the industry are expected to attend the event. The conference and the workshops will also provide delegates with ample opportunities to meet experts, network with other colleagues, and enhance their knowledge base.

To register for the event, be an Event Partner, and for all other queries, please contact:  
 Dr. Jayanti Gupta, Organizing Committee Chair  
 E: [jayantigupta@semllerresearch.com](mailto:jayantigupta@semllerresearch.com)  
 M: 9820228720

**REGISTRATION**

Fees (INR)	Preconference workshop (each) (April 19, 2012)	Conference (April 20-21, 2012)
Member*	750	3500
Non-member	1000	4000

**\*Annual membership fee is Rs. 750**  
**Registration deadline is April 12<sup>th</sup>, 2012**

To register, send check or DD payable to:  
**Indian Association for Statistics in Clinical Trials**

Address:  
 Dr. Jayanti Gupta  
 Semler Research Center  
 #75A, 15<sup>th</sup> Cross  
 1<sup>st</sup> Phase, J.P. Nagar  
 Bengaluru – 560078

**OR**

Deposit the fees to IASCT bank account and inform by email to Dr. Jayanti Gupta,  
[jayantigupta@semllerresearch.com](mailto:jayantigupta@semllerresearch.com)

Bank details are as follows:  
 HDFC Bank Ltd.,  
 Branch: K H Road, Bengaluru 560027

Beneficiary: **Indian Association for Statistics in Clinical Trials**

A/c Number : 12062020005242

# Second Annual Conference Data Driven Decisions: From Preclinical to Post-Marketing

April 19<sup>th</sup>, 2012 -- Preconference Workshops

## Clinical Trial Designs by Dr. Vishwanath Iyer & Dr. Ashwini Mathur (Novartis)

9:00 – 12:30 hrs

This workshop will provide an overview of designs used in all phases of clinical trials.

- ❖ Designs commonly used in clinical pharmacology
- ❖ Designs used in Phase 1 for finding the optimal dose - including CRM, Bayesian adaptive designs
- ❖ Designs in Phase 2 studies (2-stage, multi-stage, randomized Phase II, biomarker screening, enrichment, seamless Phase II/III, drug-drug combination, interim dose-selection)
- ❖ Designs in Phase 3 studies (adaptive designs, multiplicity including gate-keeping, group-sequential, interim analyses with sample-size re-estimation)
- ❖ A look at HA guidance, both from FDA and EMEA

## Clinical Genomics by Dr. R. Srivatsan & Dr. Swetansu Pattnaik (IBAB)

9:00 – 12:30 hrs

This workshop will focus on basic concepts of genomics, including biomarkers, and next generation sequencing. The first part of workshop will focus on some of the methods that are used to analyze genomic data, for e.g., outputs from DNA microarrays. The second part of the workshop will focus specifically on Next gen sequencing. This workshop will provide an excellent introduction to the current hot topic of personalized medicine.

Intended audience: Pharma professionals (scientists, medical writers, data managers, statisticians and programmers) who are new to the area of genetics, but work with genetic and biomarker data, and would like to have a clear understanding of the theory and science.

## Clinical Data Management – Fine tuning towards better than the best! by Mr. Deven Babre (Pharmanet-i3)

13:30 – 17:00 hrs

Designed for both new entrants and experienced data managers, you will learn good DM principles and how tasks are correlated in between Clinical and Biostatistics teams. Focus will be on:

- ❖ What should Data Manager look into a protocol and CRF?
- ❖ Possible variations a Data Manager should look for in different therapeutic areas
- ❖ Possible impact on quality / timelines & budget as a result of neglecting these variations
- ❖ Contents of ideal Data Management Plan - generic & specific – from different therapeutic areas
- ❖ Processes used by Data Manager across therapeutic areas
- ❖ Using metrics data to further improve metrics

## Meta-analysis in Risk-Benefit Evaluation by Dr. Demissie Alemayehu (Pfizer Inc. and Columbia University)

13:30 – 17:00 hrs

When data from individual randomized controlled trials are not available to inform decision about the relative risks and benefits of alternative treatment options, a systematic synthesis of available information may be a viable option. However, effective and reliable use of pooled data requires caution, since the conventional approaches are built on certain stringent assumptions and best practices. In this talk, current methodological issues in meta-analysis are highlighted, and advantages and disadvantages of alternative techniques are evaluated. Particular reference will be made to emerging topics, including meta-regression, indirect and mixed comparisons, and handling of data from non-conventional trials using case studies. The workshop is intended for applied statisticians and others involved in medical research and presupposes no previous experience with meta-analysis.

# Second Annual Conference Data Driven Decisions: From Preclinical to Post-Marketing

April 20<sup>th</sup> – April 21<sup>st</sup>, 2012 ★ Hotel Lalit Ashok ★ Bengaluru, India

## Conference Program

Day 1: 20 <sup>th</sup> April, 2012		
9:00 – 9:30	Registration	
9:30 – 9:45	Welcome Address by IASCT President	Dr. Ashwini Mathur (Novartis)
9:45 – 10:30	Plenary Address by Keynote Speaker	Dr. Tanjore Balganesh (CSIR)
10:30 – 13:00	<b>Session 1 – Pre-clinical and Non-clinical Development</b> <ul style="list-style-type: none"> <li>▪ Pharmacometrics – PK/PD modeling</li> <li>▪ Models in non-clinical development</li> <li>▪ Pre-clinical imaging for biomarkers</li> <li>▪ Modeling glucose-stimulated insulin secretion</li> </ul>	Chair: Dr. Amit Bhattacharyya (GSK)  Dr. Shashank Rohatagi (Piramal Healthcare) Dr. K S Rao (Syngene) Dr. Ritika Mukherjee (GE Healthcare) Dr. Pranay Goel (IISER, Pune)
13:00 – 13:50	Lunch	
13:50 – 14:35	Panel Discussion: How to build capabilities in clinical development to enhance communication across disciplines	
14:35 – 17:00	<b>Session 2 – Clinical Development of NCEs</b> <ul style="list-style-type: none"> <li>▪ Dose-determining studies - a Bayesian perspective</li> <li>▪ Comparison of study designs using simulation</li> <li>▪ Sample size re-estimation in late stage trials: a case study</li> </ul>	Chair: Dr. Vishwanath Iyer (Novartis)  Ms. Chethana Kalmady (Novartis) Mr. Abhishek Mishra (Sciformix) Dr. Vidyadhar Phadke (Cytel Inc.)
Day 2: 21 <sup>st</sup> April, 2012		
9:30 – 11:30	<b>Session 3 – Clinical Development of Biosimilars and Generics</b> <ul style="list-style-type: none"> <li>▪ Biosimilar development – design and statistical challenges</li> <li>▪ Clinical endpoint studies for ANDA approvals</li> <li>▪ Regulatory considerations in the design of respiratory studies for generic submissions</li> </ul>	Chair: Dr. Viraj Suvarna (Boehringer-Ingelheim)  Dr. Moumita Sinha (Biocon) Dr. Ravisekhar Kasibhatta (Lupin Ltd.) Dr. Sheetal Ingole (Manipal Acunova)
11:30 – 12:30	Poster Session	
12:30 – 13:15	Lunch	
13:15 – 14:00	Panel Discussion: Gaps & opportunities for capability development to help data-driven decision making in generic drug development	
14:00 – 16:30	<b>Session 4: Post-Marketing and Epidemiology</b> <ul style="list-style-type: none"> <li>▪ Bridging studies</li> <li>▪ Cost-effectiveness models</li> <li>▪ Maternal transmission of HIV</li> <li>▪ Epidemiology of STI and HIV in high risk groups in Tamil Nadu</li> </ul>	Chair: Dr. Chitra Lele (Sciformix)  Dr. Y. Jack Lee (LSK Global Pharma) Ms. Karen Ooms (Quanticate) Dr. Nikhil Gupte (Johns Hopkins University) Dr. L. Jeyaseelan (CMC Vellore)
16:30 – 16:45	Closing & Vote of Thanks by IASCT Secretary	Dr. Vishwanath Iyer (Novartis)