Third Annual Conference
The Journey of Evidence-Based Medicine

April 19th – April 21st, 2013 ✸ Intercontinental The LaLiT ✸ Mumbai, India



CONFERENCE SUMMARY

IASCT is pleased to announce its 3rd Annual Conference. The theme of this year's event is **The Journey of Evidence-Based Medicine.**

The conference will feature talks that will provide a historical perspective on how statistics has, and continues to play a role in evidence-based medicine. There will be half-day workshops on April 19, followed by two days of presentations & discussions.

Over 30 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 be an Event Partner, contact:
Dr. Ashwini Mathur, President, IASCT
E: ashwini.mathur@novartis.com
M: 9949489911

To register for the event and for other queries, contact: Dr. Jayanti Gupta, Treasurer, IASCT
E: jayantigupta@live.com
M: 9820228720

ABSTRACTS & REGISTRATION

Abstracts are invited for poster presentation on April 21 on topics in line with the conference theme. Email abstracts to jayantigupta@live.com by Mar 29, 2013. Best 10 abstracts will be selected and presenters can avail of the member rate for registration.

Fees (INR)	Preconference Workshop (April 19)	Conference (April 20-21)
Member	1250	3500
Non-member	1500	4000
Membership+ Conference		4250

Registration deadline is April 10th, 2013

To register, deposit the fees to IASCT bank account and inform by email to Dr. Jayanti Gupta: jayantigupta@live.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
IFSC Code: HDFC0001206

19th April, 2013 -- Preconference Workshops

Workshop 1: Introduction to Adaptive Designs across all Phases of Clinical Trials

Instructor: Dr. Vishwanath Iyer (IASCT Secretary, Novartis Oncology) 11:00 – 17:00 hrs

Description: Adaptive clinical trials are becoming increasingly common. The FDA and EMA have indicated that adaptive trials are acceptable at most stages of drug development. This tutorial will focus on the practical issues encountered when implementing adaptive designs. Special consideration will be given to systems and processes that help minimize bias and maintain trial integrity. It will also discuss the regulations, statistical considerations, logistical implications and practical applications of adaptive clinical trial designs across all phases of clinical trials.

Learning Objectives:

- Understanding the regulatory guidelines for adaptive clinical trials
- Reviewing common challenges and benefits of adaptive clinical trials
- Determining when adaptive clinical trials are applicable
- Assessing statistical considerations for adaptive design
- Examining logistical considerations for implementation such as data management, recruitment issues, analysis tools

Target Audience:

- Scientists and Statisticians engaged in designing studies
- Project Leaders
- Regulatory personnel at pharma / Biotech / CROs
- Regulators engaged in evaluating adaptive studies and their results

Workshop 2: How to Report a Clinical Trial?

Instructor: Dr. Ashwini Mathur (IASCT President, Novartis) 11:00 – 17:00 hrs

Description: Standardization in reporting of clinical trials has been used now successfully to drive excellence in conduct of clinical trials. These standardizations were based on a checklist known as CONSORT. This checklist and the associated details have been updated in 2010.

This workshop on standardized reporting of trials will be based on 2010 CONSORT guidelines.

Target Audience: Statisticians, Programmers, Medical Writers, Regulatory Teams, CRAs, Medical Monitors, Medics, Clinical trial leaders

Conference Agenda

	Day 1: 20th April, 2013	
9:00–9:30	Registration	
9:30–9:45	Welcome Address by IASCT President	
9:45–10:30	Plenary Address by Keynote Speaker: Statistics in Clinical Trials – Some emerging issues	Dr. Arun Nanivadekar
10:30–13:00	**Session 1: Evolution of statistical concepts through biometrics and then application to medical research** ▪ Healthy Numbers – Historical perspective of quantitative analysis of health ▪ Ethical conduct of clinical research: past, present & future ▪ Evolution of hypothesis testing paradigm ▪ Partake Program: Survey of public knowledge & perception of CR	 Pof. A. P. Gore, Cytel Dr. Ashwini Mathur, Novartis Dr. Vishwanath Iyer, Novartis Medanta Org
13:00-14:00	Lunch	
14:00-14:30	Sponsored Presentation: Clinical Data Integration	Saumil Tripathi, Epoch India
14:30-17:00	**Session 2: Accumulation of evidence – Data, IT & statistical considerations** ▪ Role of PK/PD modeling in study design ▪ Early Clinical Discovery ▪ Adoption of SaaS and cloud technology by pharma & CROs ▪ Emergence of focus on analysis of safety data	 Novartis TBD Perceptive Dr. Vivek Ahuja, PATH
	Day 2: 21st April, 2013	
9:30-11:45	**Session 3: Investigator-initiated research, epidemiology, outcomes research** • Evolution of hospital-based research • Applications of statistical design & analysis in alternate medicine • Epidemiology studies, patient registries • Systematic reviews, meta-analysis	Dr. Vasudeo Paralikar, KEM Hospital Pune Dr. Darshan Shankar, Indian Institute of Alternate & Integrated Medicine Dr. Sheela Godbole, NARI Dr. Unikrishnan, Manipal University
11:45-12:30	Poster Session	
12:30-13:15	Lunch	
13:15-14:00	Debate & Discussion: Are Large RCTs Passe?	
14:00-16:30	**Session 4: Use of the evidence in communications & marketing** • Interpretation & presentation of results in journals • Use & presentation of evidence while launching & marketing products • How is clinical evidence used by a prescriber? • Current state of clinical research in India	 Sunita Nair, Capita India TBD TBD Dr. Arun Bhatt, Clininvent
16:30-16:45	Closing & Vote of Thanks by IASCT Secretary	