

# Indian Association for Statistics in Clinical Trials (IASCT) presents

## Clinical Trial Interfaces, 2011

Perspectives on the collaboration between Clinical, Data Management, Biometrics,  
Medical Writing and Regulatory Functions

January 20-22, 2011 at Hotel Novotel, Mumbai

### **Registration & Payment**

To register for the conference and workshop,  
please write to Mr. Jagannatha P. S. at  
[Jagannatha.P.S@gsk.com](mailto:Jagannatha.P.S@gsk.com) with following  
details:

Name of participant:  
Name of organization:  
Name of workshop (optional):  
Member of IASCT or ISCR: Yes/No  
Postal address:  
Email address:

Send check or DD in favor of:

Indian Association for Statistics in Clinical  
Trials

to:

Mr. Jagannatha P.S.,  
Indian Association for Statistics in Clinical  
Trials,  
C/o GlaxoSmithKline Pharmaceuticals Ltd,  
#5, Embassy Links, SRT Road,  
Bengaluru-560 052

Email: [Jagannatha.P.S@gsk.com](mailto:Jagannatha.P.S@gsk.com)

OR

Deposit the amount to IASCT Bank account  
and inform by email to:

[Jagannatha.P.S@gsk.com](mailto:Jagannatha.P.S@gsk.com)

Bank details are as follows:

Name of Bank: HDFC Bank Ltd.,  
Beneficiary: Indian Association for Statistics  
in Clinical Trials

Branch: K H Road, Bengaluru 56002/  
A/c Number : 12062020005242

NOTE: No payments will be accepted  
on the day of the event.

A must attend for all clinical research professionals!

Audience will get to hear eminent personalities in this domain on  
scientific and operational aspects of clinical trials. For detailed  
agenda see next page.

Two parallel 1-day pre-conference workshops:

- ❖ Safety Report Writing
- ❖ Clinical Trial Designs  
(January 20, 2011)

Two days of conference on exciting topics ranging  
from study design, execution, to analysis,  
reporting & submissions  
(January 21-22, 2011)

### **Conference Fees (in INR)**

| For pre-conference workshops (Jan 20 <sup>th</sup> ) |                   |
|--|-------------------|
| Status   | Registration Fees |
| Member*  | 1000              |
| Non-member   | 1250              |

| For 2-day conference (Jan 21 <sup>st</sup> -Jan 22 <sup>nd</sup> ) |                   |
|--|-------------------|
| Status   | Registration Fees |
| Member*  | 3000              |
| Non-member   | 3500              |

\*Annual membership fee of IASCT: INR 750

\*ISCR members can avail the membership rate

To be an Event Partner, and for all other queries, please contact:  
Mr. Tushar Sakpal at [TSakpal@pharmanet.com](mailto:TSakpal@pharmanet.com) (Phone: 9820829124)



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January 20-22, 2011 at Hotel Novotel, Mumbai

### Conference and Workshop Details

IASCT was established as a non-profit professional organization in 2007 with the objective of enhancing the role of statistics in the pharmaceutical industry and clinical research fraternity. Visit our website <http://www.iasct.net> for more information on IASCT, upcoming events and membership details.

This unique conference is intended to bring together professionals from all functions supporting clinical trials, and provide a platform for increasing awareness and exchanging ideas on scientific and operational aspects of clinical research. The conference program has been designed to give a broad perspective on upstream and downstream activities that go into a well-designed and executed clinical study. Important regulatory considerations will also be discussed.

The conference is also expected to serve the networking needs of professionals in the industry.

#### **Two parallel 1-day workshops on January 20<sup>th</sup>, 2011 from 9am - 5pm**

##### **I: Safety Report Writing by Dr. Suhasini Sharma (Sciformix)**

This workshop will discuss the various facets of safety report writing such as:

- ❖ Global safety reporting regulations and guidelines
- ❖ Source of information for Periodic Safety Reports (RSI, regulatory websites, safety databases)
- ❖ Post-marketing (PSURs, PADERs) and developmental (EU ASR, IND AR, DSUR) reports

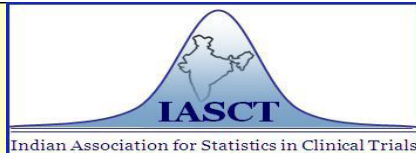
##### **II: Clinical Trial Designs by Dr. Vishwanath Iyer (Novartis)**

This workshop will discuss recent advances and innovative designs used in Phase I-III studies:

- ❖ Dose determining studies (3+3, CRM, BLRM, MCPmod)
- ❖ Clinical pharmacology studies (crossover, balance control, organ impairment, thorough QT)
- ❖ Phase II studies (2-stage, multi-stage, randomized Phase II, enrichment, seamless Phase II/III)
- ❖ Phase III studies (multiplicity including gate-keeping, group-sequential, interim analyses)



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### Conference Agenda

#### Day 1: January 21<sup>st</sup>, 2011

|              |   |  |
|--------------|---|--|
| 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. Rajendra Badwe (Tata Memorial Hospital)  |
| Session 1:   | Study Planning & Design   | Chair: Dr. Arun Nanivadekar  |
| 10:30– 13:00 | <ul style="list-style-type: none"> <li>▪ Study design: the blueprint for clinical research</li> <li>▪ Effective study planning: preparing for success</li> <li>▪ Study set-up: the roadmap for effective data collection</li> <li>▪ Selection and training of clinical research partners</li> </ul> | Dr. Prathap Tharyan (CMC)<br>Dr. Viraj Rajyadaksha (Sanofi-Aventis)<br>Indrani Kakade (Cognizant)<br>Juliet Po (Cipla) |
| 13:50 –14:35 | Panel Discussion  |  |
| Session 2:   | Study Execution   | Chair: Dr. Liesel Dsilva (GlaxoSmithKline)   |
| 14:35–16:30  | <ul style="list-style-type: none"> <li>▪ Pathway to quality management of study data</li> <li>▪ Clinical project management: who is monitoring the monitor?</li> <li>▪ Analysis planning and safety monitoring: the statistician as a trialist</li> </ul>   | Deven Babre (PharmaNet)<br>Dr. Sonal Vora (SYNERGETIK Learning Solutions)<br>Dr. Ritwik Sinha (Hewlett-Packard)        |

#### Day 2: January 22<sup>nd</sup>, 2011

|               |  |   |
|---------------|--|---|
| Session 3:    | Analysis & Reporting   | Chair: Dr. Shashidhar Rao (Novartis)  |
| 9:45 – 12:15  | <ul style="list-style-type: none"> <li>▪ Use of standards: can we really be analysis-ready?</li> <li>▪ Data analysis: demystifying the jargon</li> <li>▪ Interpretation of study results: science or art?</li> <li>▪ Medical communications: messaging to internal and external customers</li> </ul>         | Murali Ganesan (Cognizant)<br>Dr. Shailaja Chilappagari<br>Dr. Vis Niranjan (RxMD)<br>Bindu Narang (i3 Statprobe)   |
| 13:15 –14:00  | Panel Discussion   |   |
| Session 4:    | Submissions & Regulatory Interactions  | Chair: Dr. Radhika Bobba (Anhvita Consulting)   |
| 14:00 –16:30  | <ul style="list-style-type: none"> <li>▪ Regulatory interactions: engaging effectively for success</li> <li>▪ eCTD: a farewell to paper submissions</li> <li>▪ Regulatory filings: ignorance is not bliss</li> <li>▪ Comparative Effectiveness Research: from safety and efficacy to risk-benefit</li> </ul> | Dr. Manish Paliwal (Pfizer)<br>Vijay Srinivasan (TAKE Solutions)<br>Dr. Ranjani Nellore (PharMantra Consulting)<br>Dr. Viraj Suvarna (Boehringer-Ingelheim) |
| 16:30 – 16:45 | Closing & Vote of Thanks by IASCT Secretary  | Dr. Debjit Biswas (Bristol-Myers Squibb)  |