



Workshop in Pharmacovigilance: Applications of Signal Detection October 19, 2011

Organized by

Indian Association for Statistics in Clinical Trials (IASCT)

Venue

**The International by Tunga, MIDC Central Road, Andheri East,
Mumbai**

About IASCT:

IASCT is a non-profit professional organization that was founded with the objective of enhancing the role and awareness of statistics in the pharmaceutical industry and clinical research fraternity. IASCT strives to enable professional development of statisticians, statistical programmers as well as clinical research and medical professionals by organizing training sessions, meetings and conferences related to statistical techniques used in drug development and product lifecycle management.

Faculty:

Dr. Ram C. Tiwari

Associate Director, Office of Biostatistics, CDER,
FDA

Dr. Stephen E. Wilson

Director, FDA/CDER/OTS/OB/DBIII

Dr. Darshan Bhatt

Consultant: Patient Safety and Pharmacovigilance

Dr. Chitra Lele

Chief Scientific Officer, Sciformix Corp

Objective of this workshop:

The objective of this workshop is to provide a platform to discuss and create awareness about tools, techniques and applications of quantitative signal detection. A cross-functional panel of prominent and experienced speakers will cover statistical and pharmacovigilance approaches from both regulators' and practitioners' perspectives. They will focus on case studies which will help in understanding the basic concepts. The panel discussion will aim to provide an Indian context to the area of signal detection.

Intended Audience:

- Pharmacovigilance professionals, practitioners and students
- Statisticians and Programmers working in pharmaceutical research
- Clinicians, Medical writers and academicians interested in learning about signal detection

Contact: Please contact Mr. Tushar Sakpal at TSakpal@pharmanet.com or 9820829124 for any queries regarding the workshop.

Agenda:

	Topic	Speaker	Time
	<i>Registration & Tea Break</i>	<i>9:00 - 9:30</i>	
1	Development of New Data Sources for Safety Evaluation	Dr. Stephen E. Wilson (Director, FDA/CDER/OTS/OB/DBIII)	9:30 - 10:30
2	Fixed Time Signal Detection Methods with Applications	Dr. Ram C. Tiwari (Associate Director, Office of Biostatistics, CDER, FDA)	10:30-12:00
3	Case Studies using Traditional Signal Detection Methods	Dr. Chitra Lele (Chief Scientific Officer, Sciformix Corp)	12:00 - 12:45
	<i>Lunch Break</i>	<i>12:45 - 13:45</i>	
4	Pragmatic Approach to Signal Detection in Developing Countries: Panel Discussion	Dr. Urmila Thatte, Dr. Darshan Bhatt, Dr. Deepa Arora and Dr. Suhasini Sharma	13:45-14:30
5	Longitudinal/Sequential Signal Detection Methods with Applications	Dr. Ram C. Tiwari (Associate Director, Office of Biostatistics, CDER, FDA)	14:30 - 16:00
	<i>Tea Break</i>	<i>16:00 - 16:15</i>	
6	Application of Clinical Intelligence in Signal Detection	Dr. Darshan Bhatt (Consultant: Patient Safety and Pharmacovigilance)	16:15 - 17:00

Conference Fees:

Category	Annual Membership Fee*	Conference Fee	Total
New/Renewing Members	Rs. 750	Rs. 1200	Rs. 1950
Existing IASCT/ISCR Members	-	Rs. 1200	Rs. 1200
Non-members	-	Rs. 1500	Rs. 1500

*Membership for the current year is valid till March 31st, 2012. Members will get discounted rates for this and all upcoming events in 2011-2012.

Existing members due for renewal please renew your membership by paying the membership fee and get the benefit of conference fee. For membership details please send an email to: Dr. Jayanti Gupta (jyantigupta@semllerresearch.com)

Registration:

Limited seats are available and participation in the event requires pre-registration. Your registration and payment must reach us latest by **10th October 2011**.

All payments are to be made by drawing a cheque or a DD in favor of "Indian Association for Statistics in Clinical Trials" along with filled conference registration form (on page 3) and sent to:

**Mr. Jagannatha P.S.,
Indian Association for Statistics in Clinical Trials,
C/o GlaxoSmithKline Pharmaceuticals Ltd,
#5, Embassy Links, SRT Road,
Bangalore-560 052
Email: Jagannatha.P.S@gsk.com**

Or

You can deposit the amount to IASCT Bank account and send details of your transaction (either screen shot or scan copy of the bank receipt) along with filled conference registration form by email to Jagannatha.P.S.

IASCT Bank A/c information:

**Name of the Bank: HDFC Bank Ltd.,
A/C Name : Indian Association for Statistics in Clinical Trials
Branch : K H Road, Bangalore-560027
A/c Number: **12062020005242****

Conference Registration Form

1. Name of the Organization:
2. Name of Participant:
4. Current Member of IASCT: Yes/No
5. I wish to become IASCT Member: Yes/No
6. Cheque/DD Number with Date:
7. Name of the Bank:
8. Amount towards Annual Membership:
9. Amount towards Conference Fees: