

# Statistical Applications in Clinical Trials

## About IASCT

IASCT is a non-profit professional organization founded with the objective of enhancing the role of statistics in the pharmaceutical industry and clinical research fraternity. IASCT aims to enable professional development of statisticians and statistical programmers by organizing training sessions, meetings and conferences related to statistical techniques used in drug development.

## Objective

Clinical trials are the cornerstone of new drug approvals. Effective planning of clinical studies in terms of design, sample size, analysis and reporting is essential for a successful clinical trial. This workshop will focus on such critical statistical aspects which support in better, faster and cheaper drug development. Participants will learn from seasoned statisticians about various statistical considerations to be applied at planning, conduct and post-study stages of a clinical trial with case studies.

## Date & Venue

13th May, 2016  
Citrus Cunningham  
34, Cunningham Road  
Bengaluru 560 052 | India

Target Audience: statisticians/biostatisticians, programmers working in pharmaceutical industry and other public health researchers in healthcare/medical field, students pursuing courses in statistics or biostatistics or related discipline.

## Statistical Applications in Clinical Trials

### Faculty of the workshop



**Shashidhar Savanur,  
Senior Director,  
Chiltern International  
Limited**

• **Shashidhar J Savanur** is currently working as Senior Director in Chiltern Clinical Research India Pvt Ltd. Savanur has PhD degree in Statistics. Savanur started his professional career with Government of India in the Indian Statistical Service (ISS). As ISS officer he worked in various Economic Ministries, Government of India. He was head of South-Zone, National Sample Survey Organization Bangalore, before leaving Government job to take up a career in the corporate sector. In 2004 he joined GlaxoSmithKline India Pvt as Manager Statistics where he was primarily responsible for statistical analysis of Phase-I clinical trials. In 2007 he joined Chiltern Clinical Research India Pvt Ltd (then Omnicare Clinical Research India Pvt Ltd) as Associate Director.



**Vishwanath (Mahesh) Iyer,  
Head - Oncology Biometrics,  
Novartis Healthcare Private  
Limited**

• **Vishwanath (Mahesh) Iyer** is currently Head of Oncology Biometrics at Novartis, Hyderabad heading up a team of Biostatisticians, SAS programmers and Data Analysts. He is also the global head for Exploratory Safety and Statistical Analytics, Oncology. He has a Ph.D. in Statistics from Temple University, Philadelphia. Mahesh has been involved in analyzing and reporting clinical trial data since 1998 with companies like Boehringer-Ingelheim and Bristol Myers Squibb, and specifically for Oncology studies since 2000. In addition, Mahesh has also been active in the statistical research community with a primary focus on multiple comparison procedures. Mahesh is actively involved in teaching at multiple institutes in India, adjunct faculty at Institute of Ayurvedic and Integrated Medicine at Bangalore, served on the Advisory Council of India for the DIA, serves as the Secretary for the Indian Association for Statistics in Clinical Trials (IASCT), as the Vice-President of the International Indian Statistical Association – India chapter, on the Board of Studies for Statistics at Manipal University and is the co-editor for a pharmaceutical journal. He is also a Ph.D guide, currently advising 2 students.

## Statistical Applications in Clinical Trials

**Registration**  
**9.00 – 9:30 AM**

### Training Curriculum

- Introduction and motivation

- Planning of the study

- Study Designs
- Sample size
- Data Collection

- Conduct of the Study

- Interim analyses
- Sample size adjustment
- Assumptions checking
- Statistical Analysis Plan

- Post study Activities

- Reporting
- Exploratory analyses
- Interactions with Clinical



**Fees: INR 2000/-**

**Conference Registration Form**

1. Number of Participants: .....

2. Participants Information:

Organization Name	Name	Email	Contact No.

3. Payment Details:

Bank Name	Cheque/DD/Bank Transaction Number	Date	Workshop fee

**Registration:**

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 and sent to:

Jagannatha P S  
GSK Pharmaceuticals Ltd.,  
#5 SRT Road, Embassy Links  
Bangalore – 560052.  
INDIA

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  
IFSC code: HDFC0001206  
MICR Code : 560240048

You may contact Jagannath P S at [Jagannatha.P.S@gsk.com](mailto:Jagannatha.P.S@gsk.com) or 9886050820 for any queries regarding the workshop.