Indian Society for Clinical Research

Presents

Two Interesting one-day seminars on Topics Of Current Interest In Clinical Research & Biostatistics by Dr. A Lawrence Gould at Bengaluru & Mumbai, arranged by CDM & BS Council of ISCR.

Date	Time	Venue
May 24, 2011	**9:30 am to 5:00 pm**	**Fortune Park JPCelestial, Buckingham-2 Hall, 5/43, Race Course Road, Bengaluru – 560 009**
May 27, 2011	**9:30 am to 5:00 pm**	Mumbai To be announced later

A. Lawrence Gould, Ph.D.

BA (Mathematics) from Western Reserve University (1962); PhD (Biometry, minor Medicine) from Case Western Reserve University (1967). Worked at Research Triangle Institute as Statistician 1967 – 1970, at Merck Research Laboratories, various job titles, 1970 – present. Currently Senior Director, Scientific Staff. Fellow of the American Statistical Association since 1988. Member of American Statistical Association, served as Fellows Committee Chair and Publications Officer of the Biopharmaceutical Section. Member of Biometric Society ENAR, served as Secretary/Treasurer 1982-1986. Served as Editor of Journal of Biopharmaceutical Statistics 2001-2002.

Areas of research interest include use of Bayesian methods to improve effectiveness of the drug development process, adaptive trial design (including group sequential methods), evaluation of safety data from clinical trials, application of data mining and Bayesian methods to pharmacovigilance, use of data mining to identify relationships that can be used to design future trials, meta-analysis, modeling and simulation techniques to reduce cost and unnecessary patient exposure in drug development, and application of decision science methods to drug **development strategy.**

Online Registration & payment : You are requested to block your seat by registering online & payment at www.iscr.org → click on Events : Online Registration & Payment on the home page (http://www.iscr.org/Events.aspx)

Payment : Cheque / DD payable at Mumbai should be made in favor of "Indian Society for Clinical Research" for Rs. 800/- & mailed to ISCR secretariat at Mumbai (http://www.iscr.org/OfflinePayment.aspx)

EVALUATING THE SAFETY OF MEDICAL PRODUCTS

9:30 am to 1:00 pm

Main focus: Philosophy and methods for evaluating information pertaining to the safety of medical products (drugs, vaccines, devices) in a way that provides insight useful to medical practitioners.

Learning objectives: To acquire an awareness and understanding of:

1. General considerations for monitoring and evaluating safety
   a. Efficacy vs safety
2. Pre-marketing safety evaluation
   a. Conceptual framework
   b. Risk/benefit
   c. Importance of early planning
   d. Issues
   e. Triage – what needs to be analyzed, and how
   f. Effective data displays – tables and graphics
   g. Bayesian principles
   h. Screening - frequentist and Bayesian
3. Post-marketing safety evaluation
   a. Princples and general objectives
   b. Screening for associations
   c. Implementation
   d. Bayesian screening
   e. Spontaneous report vs observational databases
   f. Sequential monitoring
4. Organizational Medical Outcomes Partnership

TOPICS OF CURRENT INTEREST IN CLINICAL RESEARCH & BIOSTATISTICS

2:00 pm to 5:00 pm

Topic 1: Blinded interim evaluation of sample sizes to help preserve the power of a trial

Main focus: Practical methods for adaptive adjustment of sample size without unblinding a trial, and the statistical properties of these methods.

Learning objectives:

1. Review of various approaches
2. What blinded review is and why it works (modest mathematical level)
3. Evaluation of the statistical properties
4. Comparison of blinded evaluation with unblinded evaluation and conditional power
5. Use of principle for bioequivalence trials, where getting the sample is fast and easy, but assaying them is slow and expensive

Topic 2: Using Phase 2 information to inform the design of Phase 3 trials

Main focus: How to take information from a Phase 2 trial that may use a crossover design to directly inform the design of a Phase 3 trial that will use a parallel group design.

Learning objectives:

1. How to express models for Phase 2 and Phase 3 trials in a way that lets Phase 2 information be translated directly to a Phase 3 trial even though different designs are used
2. Use of Bayesian methods to generate realizations from joint posterior distribution of parameters
3. Using these realizations to simulate possible Phase 3 trials incorporating all sources of uncertainty

Topic 3: Timing of futility analyses and multiple futility analyses

Main focus: Incorporation of futility analyses at one or more stages of a trial to avoid carrying to completion trials that are unlikely to demonstrate a desired result

Learning objectives:

1. Trials can fail for a variety of reasons: smaller than expected treatment effect, larger than expected variability
2. Design of a trial should plan prospectively for interim evaluations to check for potential futility – this should not be done ad hoc
3. Timing of the interim looks is important
4. Evaluate potential strategies in terms of utilities

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