

Announcement
Basel Biometrics Section of the International Biometrics Society
Spring 2000 Seminar
May 18-19, 2000, Basel, Switzerland

Missing Information in Clinical Trials: Challenge or Curse?

Seminar Objectives:

The goal of the Spring 2000 seminar is to provide an “open forum” for statisticians from the pharmaceutical industry, contract research organizations and academia to share knowledge about the important statistical issues of missing information in clinical trials and to discuss them. The Spring 2000 seminar in particular should

- Introduce in the concept of missing data
- Enhance understanding of the statistical models for the types of missing information occurring in clinical trials, e.g. missing observations, drop outs, missing covariate, etc.
- Present and discuss how these models should be used in practice and can be implemented and validated
- Highlight the problems related to the Intention-To-Treat analyses
- Show how to plan prospectively for coping with missing information

Format of the Seminar:

The Spring Seminar of the Basel Biometric Section has been held every year as a one-day event. To mark the new millennium the Spring Seminar 2000 will exceptionally be held as a two-day workshop. The workshop will start at 9.00 and finish at 17.00 with a 20 minutes coffee break during the morning and the afternoon, and a 1.5-hour lunch break each day.

After each lecture about 15-20 minutes will be reserved for informal discussion with the audience. During the lectures the details of the modelling and implementation aspects of the different types of missing information will be discussed, and many examples will be presented. The validity as well as the pros and cons of the different approaches will be examined.

Organizing Committee:

Seminar Program:

Amy Racine-Poon, Novartis Pharma AG, Basel (chairperson)
Jean-Louis Steimer, F. Hoffmann – La Roche AG, Basel (co-chairperson)

Local organization:

Norbert Neumann, F. Hoffmann – La Roche AG, Basel
Klaus Opwis, Department of Psychology, University Basel
Yves-Laurent Grize, AICOS Technologies AG, Basel
Jakob Schenker, Novartis Pharma AG, Basel

Main Speakers:

Donald **Rubin**, Harvard University

Lewis B. **Sheiner**, University of California, San Francisco

Ferran **Torres**, Autonomous University of Barcelona, Spain, Co-author of the CPMP position paper on missing data.

Hans-Ulrich **Burger**, F. Hoffmann-La Roche AG

Georg **Ferber**, Novartis Pharma AG, Basel

Jim **Schimert**, Mathsoft International (S-Plus Vendor)

Fiona, **O'Callagan**, Statistical Solution Ltd (Solas Vendor)

Who should attend:

Statisticians, and practitioners with a keen interest in the application of statistics to clinical trials and drug development, from pharmaceutical companies, contract research organizations, academia, and regulatory bodies.

Registration:

Department of Psychology at the University Basel

Attn. Spring Seminar 2000

Bernoullistrasse 16

CH-4056 Basel, Switzerland

Payment should be made upon registration via bank transfer to:

- Basler Biometrische Sektion
- Account number: 16 451.593.46
- Basler Kantonalbank, PC-Number: 40-61-4.

A registration until April 14, 2000 would be appreciated.

Fees:

Company Employees	CHF 700,-
University Employees	CHF 150,-
Student (with certificate)	Free
Social event (optional)	CHF 90,-

Cancellation Policy:

Cancellations will be accepted until May 10, 2000: No refund will be made to registrants, who have not canceled by this date. Registrants are responsible for cancelling their own hotel reservations.

Cancellations must be in writing. You may transfer your registration to a colleague at any time. Please notify any such substitution as soon as possible.

Location

The workshop will take place in the large auditorium in building 71 of the F. Hoffmann-La Roche AG, Basel Grenzacherstr. 124. The entrance through building 52 (large tower) should be used.

Hotel and Travel Information:

For traveling to Basel and accomodation in Basel please check out the web site

<http://www.baseltourismus.ch>.

Social Event:

There will be an optional evening event including dinner, reasonably priced, with an emphasis on informality and relaxed atmosphere. This event will take place on Thursday, May 18, 2000. The exact location and timing of this event will be announced on site.

Attendees can secure their tickets at the time of registration at an additional charge per person. In addition, tickets will be sold on first come first serve basis at the registration desk on Thursday morning, until the end of the morning coffee break.

Draft Agenda:**Day 1**

9.00-12.00

Overview of the missing information problem in practice (H. Burger)

Overview of the conceptual framework in drug development and missing data issues (L. B. Sheiner)

Overview on statistical description of missing data mechanism (D. Rubin)

13.30-17.00

Lectures on missing observations (D. Rubin and L. B. Sheiner)

Lecture on drop out with an example in pain relief (D. Rubin and L. B. Sheiner)

Evening social program

Day 2

9.00-12.00

Lectures on missing covariate with special emphasis on retrospective meta analysis (D. Rubin).

Lectures from Health Authorities representatives (F. Torres)

13.30-17.00

Software demo (S-PLUS and SOLAS): presentation of case studies by software vendors

Panel discussion (all) on prospective planning for missing information in clinical studies

- Medical point of view (L.B. Sheiner)
- Statistical point of view (D. Rubin)
- Health authority point of view (F. Torres)
- Industry point of view (G. Ferber)

Floor discussion