Another year ends and as seems to happen every 5 years, the Society had its conference in the UK. Will we visit UK again in 2008? Another joint conference with SCT in the US in 2009? We’ll see – it all depends on you, the members of ISCB.

Until then, plans are well developed for our next 2 conferences in West and East Europe, namely Leiden in the Netherlands in August 2004 and Szeged in Hungary in August 2005 – please see this issue for more details. I’ve seen a preview of the Leiden programme and it looks very interesting...

For ISCB’s ExCom, it’s been a time of discussing many changes. Again, we have a new Office, run in Denmark by an old friend of ISCB, Rita Schou. The Society has grown a lot over the last few years and I’m sure we will all benefit from her attention to detail running the Society’s Office.

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Various issues mentioned in my report to the AGM in London (see p.13) have evolved in the meantime and I would like to update ISCB members on them.

The ISCB and SCT meeting in London was a great success scientifically and the many participants had the chance to discuss and exchange ideas. Also the organisation of the meeting was successful, and yet somehow different from the “usual” ISCB meetings. Periodically merging two different societies such as ISCB and SCT in a joint meeting has the aim of increasing the scientific exchange on biostatistics methods and applications especially between Europe and the US, the two referral areas of the Societies’ membership. All ISCB members should evaluate the joint meeting in the light of this consideration and bring their opinion to the ExCom and Officers in order to guide their decision on possible future meetings.

At a meeting between RfA representatives (who looked after the Society's Office) and the Officers, which took place in London, it was agreed that the contract between ISCB and RfA would be ended. A new contract has been signed in October between ISCB and Bjarne Nielsen of Medicon. He and Rita Schou are now acting as the new permanent office for ISCB. We already know Rita's quality of work and we are very glad she will work with us again. The Officers have done a lot to make the handover as smooth as possible, and I especially thank John Whitehead and Norbert Victor for their help.

Finally, the proposal for the 2005 meeting in Szeged, Hungary, submitted by Julia Singer, was approved in London, and I would like to thank Julia for the hard work she has been doing since then to make the first steps in the organisation. In the meantime I invite you all in Leiden next August!

I wish you all a fruitful and happy 2004.
## Books for Review by Harry Southworth

### Books for Review

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<tr>
<th>Author(s)</th>
<th>Title</th>
<th>Publisher (year) ISBN</th>
<th>Reviewer</th>
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<tr>
<td>Giovanni Parmigiani, Elizabeth S. Garett and Scott L. Zeger (Eds.)</td>
<td>The Analysis of Gene Expression Data</td>
<td>Springer (2003). 0-387-95577-1</td>
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### Books reviews in this issue:

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<tr>
<td>Shein-Chung Chow, Jun Shao</td>
<td>Statistics in Drug Research: Methodologies and Recent Developments</td>
<td>Marcel-Dekker (2002) 0-8247-0763-X</td>
<td>Arne Ring &amp; Gerhard Nehmiz, Germany</td>
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<td>Henry C Thode, Jnr</td>
<td>Testing for Normality</td>
<td>Marcel-Dekker (2002) 0-8247-9613-6</td>
<td>Peter Lachenbruch, USA</td>
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### Books reviews in the next issue:

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<tr>
<td>Jay E Gould</td>
<td>Concise Handbook of Experimental Methods for the Behavioural and Biological Sciences</td>
<td>CRC Press (2002) 0-8493-1104-7</td>
<td>Elisabeth Svenssson, Sweden</td>
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<tr>
<td>Shein-Chung Chow &amp; Jen-Pei Liu</td>
<td>Design and Analysis of Bioavailability and Bioequivalence Studies</td>
<td>Marcel-Dekker (2000) 0-8247-9613-6</td>
<td>Laszlo Endrenyi, Canada</td>
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<td>Aviva Petrie, Caroline Sabin</td>
<td>Medical Statistics at a Glance</td>
<td>Blackwell (2000) 0-632-05075-6</td>
<td>Zdzislaw Wisniowski, Poland</td>
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<td>Richard Farmer, David Miller, Ross Lawrenson</td>
<td>Epidemiology and Public Health Medicine</td>
<td>Blackwell (1996) 0-86542-61-2</td>
<td>Michael Di Marino and Nicole Close, USA</td>
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Books for Review (continued)

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<tr>
<td>Mikel Aickin</td>
<td>Causal Analysis in Biomedicine and Epidemiology: Based on Minimal Sufficient Causation</td>
<td>Marcel-Dekker (2002) 0-8247-0748-6</td>
<td>Rosa Jiménez</td>
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<td>Martin J Crowder</td>
<td>Classical Competing Risks</td>
<td>Chapman&amp;Hall/CRC (2001) 1-59488-175-5</td>
<td>Dario Gregori</td>
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<tr>
<td>Kirkwood</td>
<td>Essentials of Medical Statistics</td>
<td>Blackwell</td>
<td>Dick Bezemer</td>
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Books sent for review a long time ago

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<tr>
<td>Donald C Monkhouse &amp; CT Rhodes (Eds.)</td>
<td>Drug Products for Clinical Trials</td>
<td>Marcel Dekker (1998)</td>
<td>Koos Lubsen</td>
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Book publishers’ webpages:

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<td><a href="http://www.medirect.com/">http://www.medirect.com/</a></td>
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<td><a href="http://publishing.cambridge.org/stm/mathematics/stats/">http://publishing.cambridge.org/stm/mathematics/stats/</a></td>
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<td>Marcel Dekker</td>
<td><a href="http://www.dekker.com/catalog/search.jsp?category=%2FStatistics">http://www.dekker.com/catalog/search.jsp?category=%2FStatistics</a></td>
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<td>Oxford University Press</td>
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<td>John Wiley &amp; Sons</td>
<td><a href="http://catalog.wiley.com/">http://catalog.wiley.com/</a></td>
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Important note to potential reviewers:
We regularly receive books from publishers for review in the Newsletter. We are most grateful for these “donations”, the reviews of which we regard as a service to you, our members. Regrettfully, some individuals, despite repeated reminders, neither return a review, nor the book to ISCB... When requesting a book, please remember that you’re making a commitment to the Society to do a little work in return for keeping the book. **Please do a little work in return for keeping the book and your name will be published in the News!**

For the format and length, please see recent issues of ISCB News. You can send the review in a variety of formats but plain text email, html, RTF or Word are preferred. The reviews may be edited for clarity (English grammar and spelling, punctuation etc.).
This book will not disappoint ISCB members familiar with the author’s presentation style at conferences. There is the same clarity of exposition, with argument based on reasoned common sense. There is also the same level of controversy. In addition to what was, at the time of the first edition, an unconventional approach to cross-over design and analysis, there are many asides aimed at conventional practices in parallel trials and elsewhere in clinical research.

The introduction describes and explains the advantages and disadvantages of cross-over designs. It also sets the philosophical stance. In particular, each cross-over trial will form a small part of a research portfolio. This stance is applicable in practice to the pharmaceutical industry more so, perhaps regrettably, than to the public sector.

An ‘optional’ mathematical chapter is followed by a progression from the AB/BA design with normal and non-normal data, through designs involving more than two treatments where each recipient receives each treatment once, to less common designs such as factorial and ‘n of 1’ studies. Analyses are demonstrated by calculator and by using SAS, GenStat and S-PLUS commands. Recommendations for design and analysis are refreshingly clear. As a reference book however it may be difficult to dip into these chapters without having read the preface and introductory sections.

One of the practical difficulties of cross-over trials in the literature is that reports are often too vague. A chapter on graphical and tabular presentation gives clear guidance, and comments on common poor practices. Graphical methods used to illustrate examples throughout the book are excellent.

There is a brief chapter on design issues, including particularly clear advice for washout phases. In a further ‘optional’ chapter, the author makes a strong defence of the AB/BA design, and details his reasons for opposing models of ‘simple carry-over’.

The target audience is statisticians without previous experience of cross-over designs and physicians carrying out or interpreting cross-over trials. As such, several of the more mathematical sections are ‘starred’ as unnecessary for the physician. I would have no hesitation in recommending this book to all clinical trials statisticians, regardless of their experience with cross-over designs. Nor would I hesitate to recommend Chapters 1 (introduction) and 8 (graphical and tabular presentation) to physician colleagues interested in cross-over designs.

The preface notes that some additions are in response to a review of the first edition. If this is an invitation to make requests for the third edition, I would like to see more on practice rather than theory. For example, physicians would benefit from advice on critical appraisal of published trials, and on how the design is used and misused in practice beyond the regulatory framework.

Some general comments follow. There are little asides about common practices elsewhere: carry-over in parallel trials (Chapter 1), assumptions of independence in multi-centre trials (Chapter 2), misinterpreting non-significance as proof of null, mid p-value (Chapter 4), repercussion of blinding in equivalence trials (page 124), use of C\text{max} and T\text{max} in pharmacokinetics (Chapter 7), ritual of sample size calculations (Chapter 9). The book usually flags when points are general to all trials.

Some comments on specific chapters follow.

Chapter 2: Mathematical but also philosophical. Argues for consistency: if a factor is worth balancing in design, it should be incorporated in analysis.

Chapter 3: AB/BA cross-over with normal outcome. The large proportion of starred sections doesn’t help the flow. Some bits that are not starred are unnecessarily mathematical (e.g. references back to Chapter 2 results, and baseline measurements showing working by calculator). Inclusion of sections for analysis by SAS (and appendices for GenStat and S-Plus) implies that the chapter is aimed more at statisticians than medics. There are some unusually and refreshingly clear recommendations at end.

Chapter 4: AB/BA non-normal. Information on transformations not specific to cross-over. Non-parametric general discussion and calculations, clear preference for parametric when possible. Binary, ordinal and frequency data largely beyond medics but not starred.

Chapter 5: More than 2 treatments, normal data. Actually, just each treatment once for every patient designs. Tricky to dip into without recognising previous comments regarding carryover and multiple comparisons. Notes such as differences between Latin squares in agriculture (all options affecting others) and in cross-overs (time effect).


Chapter 7: Special designs. Factorial and incomplete blocks: only ‘remark’ on design issues. It is a bit frustrating to be given worked examples of methods not used in practice or recommended. N-of-1 and bioequivalence study recommendations for analysis and honesty to patients.

Chapter 8: Graphs and Tables. Clear recommendations and comments on common (bad) practices. Why so late in book?

Chapter 9: Design issues. Offers and dismisses means to calculate preference between parallel and cross-over. Clearer on washout phases. Scant on choosing sequences and sample size.

Chapter 10: Maths of carry-over. Strong defence of AB/BA design and criticism of ‘simple’ carryover models.
In the last News, I asked “Are the days of the paper ISCB News numbered?” and the conclusion the Communications Subcommittee and Executive Committee reached in London was “Yes, but…” We will continue to produce a paper News for a little while yet, but in 2004 will test out the publication of an e-News. As this may become the only means of distributing your News in the future, we must have your email address in the Society’s database so that we can send you the e-News, or more likely a link to the e-News on the webpage.

Back in December 1999, I wrote “We are also in the process of setting up an emailing list, both for informing members of books for review and future events, and for discussing topics of interest to ISCB members. I do hope many of you will take part in this new venture”. Since then, I’ve added all the members whose email addresses were available to the list. As then, this represents a sizeable 700 out of the 800 members. Only a few people have asked to be unsubscribed or have unsubscribed themselves.

A reminder about security: I wanted to avoid ISCB members getting any junk email. So the lists were set up as follows:

- Only ISCB members can join. People who don’t renew will be removed.
- Messages are moderated to avoid messages accidentally being sent to the list.
- Nobody else has access to the email list. The yahoogroups service is paid for by small email advertisements that appear at the bottom of messages.

My main problem with administrating the email list is one I was “warned” about! Lutz Edler told me that it’s quite common for messages to “bounce” i.e. be returned to sender when someone’s email address has changed (e.g. company merger) or has been deleted (they moved jobs). Occasionally, this may be due to an intermittent computer problem, so I try once more to get a reply from the email address, or ask a colleague with a similar email address if that person is still there. Nevertheless, this is time-consuming and often fruitless. So, please keep the ISCB Office up to date with your email and address changes! All it takes is an email to the Office.

So what has been sent to the members on the emailing list? A few announcements, of courses and conferences, and recently the Books for Review which hadn’t been requested after the last News was published, as well as some new ones. This has been a great success with the 20 or so books attracting potential reviewers from around the globe. Book reviewers who haven’t renewed their ISCB subscription are sent a reminder and if no positive response is given, they won’t be considered eligible to receive a book.

How do you join the ISCB yahoogroup? Simply send an email to:

`iscb-subscribe@yahoogroups.com`

Please note that I monitor the requests to join and I compare them with the membership list so that only members may join. In this way, a private list is maintained: nobody outside the list has access to any information.

To Unsubscribe, send a message to:

`iscb-unsubscribe@yahoogroups.com`

Non-renewers will be reminded to renew their subscription, and if nothing is heard, they will be removed from the yahoogroup.

To send a message to ISCB, send it to:

`iscb@yahoogroups.com`

Please note that I monitor the email sent to the list so that the ISCB membership does not receive completely irrelevant messages. As time goes by, we will build up an idea of what the list can be used for.

As well as the ISCB yahoogroup, I’ve also set up email lists for various subcommittees and conference local organising and scientific programme committees. Within these groups, people can communicate within the groups. Again, messages can be sent to the group, but these won’t be sent to the group unless it’s requested it’s open to such external messages.

The complete list is:

**ISCB, ExCom and Subcommittees:**

- iscb
- iscb-excom
- iscb-conf-org
- iscb-education
- iscb-reg-aff
- iscb-dentist
- iscb-national-groups
- iscb-stud-conf-awrd

**Programme Committees:**

- iscb-Leiden-loc
- iscb-Leiden-spc
- iscb-Szeged-loc
- iscb-Szeged-spc

Programmes are called to communicate easily with the entire group. Messages sent to a group by a non-member will be sent to the chair of the group for appropriate disposition.

If you have any comments about ISCB yahoogroups, please contact me.
When I received this book from the editors and opened it to the Contents, I was struck by a sense of déjà vu. Two years earlier, my colleagues in the Johns Hopkins Centre for Clinical Trials and I had developed an outline for a two-day course entitled "Monitoring Treatment Effectiveness and Safety in Clinical Trials". The contents of this book are remarkably similar to our course outline, with the exception of the final chapter and the appendix.

This book is one in the series of texts Statistics in Practice. In addition to the table of contents, it consists of a preface, 10 chapters, an appendix, and an index. In Chapter 1, the authors provide an overview of the topics addressed in more detail in later chapters. They conclude with four fundamental principles of data monitoring. A few of the examples discussed throughout the book to illustrate issues and dilemmas of data monitoring committees also are introduced in Chapter 1.

In Chapter 2, the charge and responsibilities of data monitoring committees are the focus. The authors point out that the charge may be broad or narrow, depending upon the sponsor, the nature of the trial, and the potential risks to trial participants (patients). Both scientific and practical tasks are discussed. The authors advocate development of a formal charter for the data monitoring committee before formal monitoring activities begin.

In Chapter 3, the focus is on the composition (membership) of the data monitoring committee. This discussion leads naturally into Chapter 4, which focuses on the importance of independence of the members and avoidance (or management) of potential conflicts of interest of members, and then issues of confidentiality and the need for unmasked data for review by the data monitoring committee (Chapter 5).

In Chapter 6, the authors discuss meetings of the data monitoring committee, including practical issues of timing of meetings, preparation of data reports, meeting format, and minutes.

Chapter 7 deals with interactions of the data monitoring committee with other components of the trial organization, including the sponsor and the trial investigators, institutional review boards, regulatory agencies, advocacy groups, and data monitoring committees for other trials.

In Chapter 8, the authors discuss statistical, philosophical, and ethical issues in data monitoring. This chapter includes an overview of statistical methods for monitoring for both beneficial and harmful effects of treatments, approaches to subgroup analyses and interpretation, and monitoring issues for primary outcomes versus secondary outcomes. Discussion of ethical issues focuses primarily on circumstances that warrant early termination of a trial.

Chapter 9 describes settings in which an independent data monitoring committee is needed and alternative approaches to meeting monitoring needs. In the final chapter (Chapter 10), the authors discuss interactions between the U.S. Food and Drug Administration and data monitoring committees.

The Appendix is an outline of the data monitoring committee charter advocated by the authors in Chapter 2.

Each chapter of the book begins with "Key Points" to be discussed in the chapter that are set off within a box. Each chapter ends with bibliographic references, many of which were familiar to me but also many of which I was unaware.

A major strength of the book is the extensive experience of the three authors with data monitoring committees in clinical trials. In the preface, the authors also credited a distinguished list of clinical trialists with reviewing drafts of chapters and contributing illustrative examples. The examples are drawn largely from trials conducted in the U.S. under government sponsorship and also from multicentre, parallel group treatment and prevention trials in which drugs or other pharmaceutical agents were evaluated. This focus is the major shortcoming of the book. Not surprisingly, based on the trials and medical specialty areas with which these authors have been associated, examples were drawn primarily from trials in cancer, cardiovascular disease, and AIDS. Although the principles and many of the issues presented are equally applicable to trials of surgery, behavioural modification, and other interventions, more examples from such trials and other medical settings would have enhanced the usefulness of this book.

Despite these minor quibbles, I found this book to provide both broad and deep discussions of data monitoring committees and issues that have confronted them. I recommend the book to both new and experienced clinical trialists, especially statisticians who may serve either as trial statisticians responsible for presenting accumulated data to data monitoring committees or as members of data monitoring committees and physicians who may have only one or a few opportunities to serve on such a committee. Every new chair of a data monitoring committee should be given a copy of this book. It also would be a useful textbook for a course (or section of a course) on data monitoring principles and practices, particularly if supplemented with examples from trials in other medical areas and with test interventions other than drugs.
ISCB26 Szeged: 21-25 August 2005

This is the second time the scientific meeting of the ISCB will be held in Hungary. In 1996, before ISCB17, we invited you before, writing that “the atmosphere of Budapest is like the inverse of the mythological river of oblivion called Lethe – those who taste it can never forget” (see ISCB News, June 1996 – how nice is to leaf through such old papers). This can be one, subjective, reason for you to come again. And there is an objective one as well: we hope to have a scientific programme covering a wide range of topics.

Szeged is a university town with approximately 150,000 inhabitants and 20,000 students in different colleges. Its churches, historical buildings and colleges give a unique atmosphere to the city, blending its traditional and modern features.

More details will be available in the First Announcement you will receive in spring 2004. Soon a homepage will be created:

http://www.congresstravel.hu/iscb

Scientific Programme Committee:
Michael Schemper, chairman, Austria
Axel Benner, Germany
Leon Bobrowski, Poland
Mike Campbell, UK
Daniel Commenges, France
Denis Enachescu, Romania
Krista Fischer, Estonia
Nancy Geller, USA
Els Goetghebeur, Belgium
Robin Henderson, UK
Zsolt Lang, Hungary
Luigi Mariani, Italy
Jana Zvarova, Czech Republic

Local Organising Committee:
Júlia Singer (chair)
Krisztina Boda
Tibor Nyári
ISCB25 Leiden, Netherlands 2004: Conference Awards for Scientists

From Michael Schemper

Conference Awards for Scientists are available for biostatisticians from ISCB target countries (in particular countries of Central and Eastern Europe as well as Third World countries) to attend and present a paper at the 25th ISCB Meeting in Leiden, Netherlands, 15-19 August 2004. Up to six such awards will be granted. An award consists of free accommodation and registration paid by ISCB. Scientists should submit the application form and a one-page summary of the paper to be presented. For full details of the scheme, which should be studied prior to preparing an application, and for the application form please write to

Michael Schemper
Chairman, ISCB Subcommittee on 'National Groups'
Department of Medical Computer Science, Section of Clinical Biometrics
Vienna University
Spitalgasse 23
A-1090 Vienna, AUSTRIA

Tel: +43 1 40400 6689
Fax: +43 1 40400 6687
email: Michael.Schemper@AKH-Wien.ac.at

The closing date for application is Monday 1 March 2004.

ISCB25 Leiden, Netherlands 2004: Student Conference Awards

From Marie Reilly

Student Conference Awards are available for registered postgraduate students to attend and present a paper at ISCB25 in Leiden, Netherlands, 15-19 August 2004. It is intended that at least 3 awards will be made. Selection will be made on the basis of a summary of the paper to be presented, which should illustrate the application of statistical methodology to clinical or epidemiological research. Results of particular studies are of interest only if the analysis has methodological implications or shows a novel and interesting application of biostatistics.

Applications, prepared as described below, should be sent to

Marie Reilly
Chair, ISCB Student Conference Awards Subcommittee
Dept. of Medical Epidemiology & Biostatistics
Karolinska Institutet
PO Box 281
Nobels vag 12A
S-171 77 Stockholm
Sweden

Tel: +46 8 728 39 82
Fax: +46 8 31 49 75
email: Marie.Reilly@meb.ki.se

The closing date for applications is Monday 1 March 2004.
From Bettina Hansen

On behalf of the Local Organising Committee, we warmly invite you to participate in the 25th Annual Conference of the ISCB, which will be held from 15-19 August 2004 at the Holiday Inn Hotel in Leiden, The Netherlands.

Leiden is a historical town located in the western part of The Netherlands close to major cities such as Amsterdam and The Hague and conveniently close to the Amsterdam International Airport, Schiphol.

Leiden University was founded in 1575 and is the oldest university in The Netherlands. The Department of Medical Statistics of the Leiden University Medical Centre (LUMC) is the largest and one of the oldest medical statistics departments in The Netherlands. Its members have always played an active role in the ISCB. The department is proud to be the host institution for the ISCB 2004.

The Local Organising Committee and the Scientific Programme Committee are working hard to set up the organisational structure and the social programme and to put together an interesting programme that meets the demands of present day clinical biostatistics.

We are most pleased to invite you to join the 400 international participants we are expecting at our conference. All participants are encouraged to submit abstracts for the ISCB 2004. Abstracts for oral or poster presentations may be submitted electronically by visiting our website: http://iscb2004.clinicalresearch.nl/ All abstracts must be received by the Scientific Programme Committee no later than Monday 1 March 2004.

We look forward to seeing you in Leiden at what promises to be a very rewarding and stimulating event!

Hope to meet you then.

Hans van Houwelingen, Chair Local Organising Committee
Theo Stijnen, Chair Scientific Programme Committee

Conference Website: http://iscb2004.clinicalresearch.nl/

Important dates
- 1 March 2004: Final date for submission of abstracts and application for ISCB Conference Awards (Scientists and Students)
- 1 May 2004: Notification of accepted abstracts
- 1 June 2004: Final date for early registration
- 15-19 August 2004: Conference
Chapter 1. Introduction (p.1-30)
1.1 Process of Drug Development
1.2 Regulatory Requirements
1.3 Good Pharmaceutical Practices
1.4 Good Statistics Practice
1.5 Aim of the Book and Outline of Practical Issues
Chapter 2. Pharmaceutical Validation (31-52)
2.1 Regulatory Requirements
2.2 Standard Curve
2.3 Calibration
2.4 Assay Validation
2.5 In-Process Controls and Validation
2.6 Multiple-Stage Tests
Chapter 3. Dissolution Testing (53-76)
3.1 USP/NF Dissolution Test
3.2 Probability of Passing the Dissolution Test
3.3 Dissolution Profile and Similarity
3.4 Methods for Assessing Similarity
3.5 Chow and Ki’s Method
3.6 Chow and Shao’s Method
Chapter 4. Stability Analysis (77-106)
4.1 Statistical Model and Design
4.2 Testing for Batch-to-Batch Variation
4.3 Shelf-Life Estimation
4.4 Two-Phase Shelf-Life
4.5 Discrete Responses
4.6 Multiple Components/Ingredients
Chapter 5. Bioavailability and Bioequivalence (107-146)
5.1 Average, Population, and Individual Bioequivalence
5.2 Statistical Design and Model
5.3 Statistical Tests Suggested by the FDA
5.4 Alternative Designs for IBE
5.5 Tests for PBE
5.6 In-Vitro Bioequivalence
5.7 Sample Size Determination
Chapter 6. Randomization and Blinding (147-168)
6.1 Randomization Models
6.2 Randomization Methods
6.3 The Number of Centres
6.4 Effect of Mixed-Up Treatment Codes
6.5 Blinding
6.6 The Integrity of Blinding
6.7 Analysis Under Breached Blindness

This monograph provides a broad overview on current statistical methods used in pharmaceutical industry. Topics from preclinical, clinical and non-clinical statistics are presented, well structured into twelve chapters for easy reference. Already the table of contents, together with the introduction in Chapter 1, provides an overview on statistical analysis in drug research, which could be given to each scientist in drug industry to understand the importance of statistics to ensure the safety and efficacy of the investigational drug on the one hand and the quality of drug manufacturing on the other. The selection of topics is generally in accordance with our experience. They are always presented with a nice introduction, followed by some details of the statistical methodology in about 30 pages for each chapter.

The introductory character of the book does not allow presenting the statistical algorithms in depth, but this restriction is prudent with respect to the target group of the readership which clearly transcends the group of biostatisticians or regulatory affairs specialists. Practical applications are given frequently to illustrate the algorithms.

We want to show the contents of the texts based on two examples: In Chapter 5, all relevant approaches of establishing bioequivalence (average, population and individual) are explained, based on current FDA guidelines. In addition, alternative designs and tests are shown and their respective advantages are explained in detail regarding e.g. unbiasedness of estimators or power. As in the other chapters, special emphasis is put on sample size determination for each case.

In Chapter 7, the concept “substantial evidence” is interpreted and split into the components “generalisability” and “reproducibility” of clinical trials. The “reproducibility” is here defined as the probability of reproducing a small p-value of the first trial in a second one, and its calculation is explained with various known and recent methodologies. “Generalisability” is restricted to the explanation of small differences between means and standard deviations, but does not include medical or mechanistic generalization.

One disadvantage of the book is the strong focus on FDA guidelines and opinions, only marginally mentioning the ICH in the first chapter.

Some currently important statistical topics are not explained. For example, the analysis of pharmacokinetic data is restricted to bioavailability and bioequivalence, while modern statistical aspects to pharmacokinetic analyses (e.g. dose proportionality, modelling in population PK) are neglected.

The reference of literature is large, but not as wide and comprehensive as would be expected for an overview of biostatistics. The citation of a large number of the authors’ own references shows that a broad discussion on recent developments was not their focus. Also the subject index appears to be too small. In addition, our expectations of finding updated information on current developments, additional references for further reading and links to international guidances on the publisher’s internet site of the book were not fulfilled.

As a conclusion, we can recommend this book as a reference which can help different groups to understand current methodologies and applications of statistics in drug industry. It provides a nice and clearly structured overview on each topic and may lower potential barriers for further studying each area.
The Annual General Meeting (AGM) was held at the conference site on Monday 21 July 2003, from 1330 to 1430, during lunch.

The agenda of the meeting was:

1. President’s report
2. Treasurer’s report
3. Subcommittee reports and motions for continuation: Subcommittee on National Groups Subcommittee on Communications Subcommittee on Statistics in Regulatory Affairs Subcommittee on Education Subcommittee on Student Conference Awards Subcommittee on Statistics in Dentistry Subcommittee on Conference Organisation
4. Report on the 2002 elections for the Executive Committee
5. Future ISCB meetings
   - 2004: Leiden (The Netherlands)
   - 2005: Cancelled meeting in Krakow (Poland)
   - 2005: Szeged (Hungary)
6. Any other business

**President’s report (MGV)**

The hand over between 2002 and 2003 was quite extensive: other than myself becoming the new president, and John Whitehead the new vice-president, we also had a new treasurer (Norbert Victor) and two new members in the Executive Committee (Bjarne Nielsen and Koos Zwinderman), together with other six members renewed. The first occasion to meet is here in London, but many other contacts have already been going on by Email. The transition went very smoothly thanks to a lot of support from Simon Day, now past president, whom I wish to thank again, and to John Whitehead who efficiently helped the new treasurer to step in.

I particularly welcome the new members of the ExCom and wish them a fruitful period of work with and for the Society. The ISCB meeting in Dijon, last year, was scientifically very successful and very pleasant, and we thank again Harbajan Chadha-Boreham and Stephen Senn for their work in organising the meeting and the scientific programme, respectively. The meeting was also successful financially and this was very important for the Society, which needed to recover from a marked loss which occurred in the previous year’s meeting. The Society still needs to be cautious in the near future with its financial reserves, and much will depend on this current meeting budget, before we can say we have again a stable and safe reserve level.

Communication among officers was rather intense during the first semester of the year and it concerned mainly:

1) The organisation of this joint meeting. Some issues required discussion and clarification in the effort of harmonising the procedures and the expectations of the two Societies. However, I think we all be able to appreciate the richness that comes from merging two different scientific and organisational experiences. We were very pleased on how the organisation worked and we are especially thankful to Mary Karpers-Burke, from the SCT office, who played a very important role in it.

2) The new permanent office: RfA (Resources for Association now, formerly Resources for Business). The officers have been evaluating various aspects of the first period of work with RfA with the aim of making recommendations, at the end of the first year, on the actual contract and procedures.

3) The setting up of two new subcommittees. I am glad to announce that the Subcommittees approved at the ExCom in Dijon have now their terms of reference approved by the officers and a good number of members. I express my thanks to Emmanuel Lesaffre who is chairing the new Subcommittee on Statistics in Dentistry and to Harbajan Chadha Boreham who is chairing the Subcommittee on Conference Organising. Both will have their first meeting here in London, and I think their work will be very useful for the Society.

I shall say little about the subcommittees which have been now actively operating in ISCB for various years, as you will be presented their reports. I wish to mention also the (as yet) unseen work of Hans van Houwelingen and Theo Stijnen who are chairing the Local Organising Committee and the International Scientific Committee, respectively, for the 2004 ISCB meeting in Leiden. We all look forward to this meeting which promises to be first class!

As for the following years, the previously scheduled 2005 meeting in Krakow will not take place because, due to personal problems, Ewa Kawalec had to withdraw her candidacy. We thank her for all the work she had already done on the project and hope it will be possible to set up a meeting in Krakow in the future. We are now considering for 2005 a new proposal for a meeting in Szeged, which was submitted by Julia Singer, from the Hungarian group, and looks very promising. The following years are awaiting new proposals and all active ISCB members are invited to consider the challenge of organising an exciting annual meeting for the Society.

Finally, I take the opportunity to thank all people who have been contributing to ISCB, and in particular the Officers with whom I found cooperation was always easy and very fruitful.

**Treasurer’s report (NV)**

1. At the end of 2002, the society’s equity capital stood at £53,409.34, compared with £54,894.23 at the end of 2001. This is a reduction of £1,484.89 following the reduction of £49,411.30 in 2001. In fact, there is also a loss this year, but it is small compared to the losses in the years 2001 and 2000. It seems that we have been successful in stabilising the society’s finances for 2002 due to a surplus of the Dijon conference (see 2.)

2. Concerning the Dijon conference, a surplus of £13,049.48 could be registered as income; we should be very thankful to the Dijon organisers to handle this conference in the way they did. However, it should be mentioned that this surplus comprises a considerable amount of waived congress fees for officials and of other payments for ISCB. Therefore, the real surplus for ISCB is smaller.

3. The London congress 2003 has been handled in a very effective way by the central office of SCT. But, according to current estimates, we will end up with a deficit!


5. Last year’s economy measures are apparently not sufficient to reach our aim to return to an equity of £100,000; in contrary, we have to expect a further loss in 2003. We will try to strengthen the economy measures, but we feel obliged to propose an increase of the membership fees for the future.

6. The full membership fee of the Society will be €40,- for the year 2003.

**Remarks:** As it can be seen from indicating the membership fees in Euros, we intend to change from British pound to Euro. To facilitate the judgement of the (small) increase: it is about £5/year. The Treasurer’s report was approved unanimously by the ISCB participants at the AGM.
Subcommittee Reports
The seven Subcommittee Chairs reported on the activity of their Subcommittee, and their complete reports are published together with these minutes in the Newsletter, with terms of reference and list of members. The reports of the seven Subcommittees to the AGM were (edited by the Secretary):

Michael Schemper on National Groups
A total of 10 applications for the Conference Awards for Scientists for the London ISCB24 meeting were received. The National Groups Subcommittee voted to select the following 6 winning entries: Antoni L. Dawidowicz, Poland, Maria Fazekas, Hungary, Yasemin Genc, Turkey, Ülle Kirsimägi, Estonia, Tiberiu Postelnicu, Romania, Jeno Reiczigel, Hungary. The motion for continuation of the Subcommittee was approved by the ISCB participants at the AGM.

David Warne on Communications
With the early annual ISCB meeting in 2003 organised jointly with the SCT in London (20-24 July) the Newsletter had to appear in April 2003. For this reason it will be tried to establish an E-Newsletter together with the Webmaster (Silvia Codony) for September 2003. After a hectic 2001-2 coping with changing to a new Permanent Office, overall, and more specifically the cooperation with the Office staff through J. Fox, work has gone more smoothly in 2002-3. The News is now printed more cheaply on better quality paper. A new Book (assistant) Editor started in 2003: Harry Southworth (replacing Caroline Jackson). In 2002 approximately 30 books were distributed to be reviewed. Thanks to the advice from the ExCom and Subcommittee on Communications, the tracking of books and reviews is being done more closely than before and appears to be working.

Some miscellaneous comments are: Simon Day has left the SC to be replaced by MGV. The new advertising policy, worked out in Dijon, has collected £900 this year.

The News has now been attractive in publishing the lists of members. The reports of the seven Subcommittees to the AGM are published together with these minutes in the Newsletter, with terms of reference and list of members. The reports of the seven Subcommittees to the AGM were (edited by the Secretary):

Jorgen Seldrup on Regulatory Affairs
Two Points to Consider (PtC) documents on which the Subcommittee commented in the past have now been adopted by CPMP:

1. CPMP/EWP/908/99 “Points to consider on multiplicity issues in clinical trials” was adopted in September 2002
2. CPMP/EWP/2863/99 “Points to consider on adjustment for baseline covariates” was adopted in May 2003

While it is hard to directly identify which of the comments made by the Subcommittee have been taken note of, it is clear that many ISCB general and specific comments have been recognised. During the past year our comments on past PtCs have been made available at our Subcommittee website (go to iscb-homepage.org and click on subcommittees). Our comments on a NICE document are also available on the website. At the time of preparing this report our comments to WHO on CIOMS was still in the process of being put up. There have been no new PtCs available for comment in the past year. It is expected that the PtC on “Choice of delta” (CPMP/EWP/2158/99) will be released for comment after the next CPMP Efficacy Working Party meeting in July. However, there is currently no news on the availability for comments of a PtC on “Methodological Issues in Confirmatory Clinical Trials with Flexible Design and Analysis Plan” (CPMP/EWP/2459/02)

The motion for continuation of the Subcommittee was approved by the ISCB participants at the AGM. As the ISCB24 meeting was held in London, the host country, the meeting webpage has been updated and new look is more attractive. The new advertising policy, worked out in Dijon, has collected £900 this year.

The number of applications increased from nine in 2001 to fourteen in 2002, and 34 this year (2003). However, some of this year’s increase is likely due to the joint conference, so we still wish to actively work to encourage even greater participation in the years ahead. All members of the subcommittee commented on the high standard of the entries, with many excellent methodological and applied papers. The task of judging this good work was a very difficult one, as there is no simple formula for comparing quality work of a methodological and applied nature. We co-ordinated the work this year with Steve Goodman of the Society for Clinical Trials with whom we are having a joint conference, and the student award committees of both societies judged the papers.

There were 34 applications in 2003. There were four winners and two “honourable mentions” chosen. The winners are invited to present their paper in an oral presentation at the London conferences, and the best presentation will be awarded the Thomas Chalmers Memorial Award. The “honourable mentions” were invited to contribute a poster presentation. The total cost of the Student Awards for 2003 are likely to be approximately €7,000 ($8500): a fixed amount of $1750 for each of the winners and $750 for each of the “honourable mentions”. This is to be shared equally by ISCB and SCT, so that the cost to ISCB of this years awards will be approximately £3,500.

The number of applications increased from nine in 2001 to fourteen in 2002, and 34 this year (2003). However, some of this year’s increase is likely due to the joint conference, so we still wish to actively work to encourage even greater participation in the years ahead. All members of the subcommittee commented on the high standard of the entries, with many excellent methodological and applied papers. The task of judging this good work was a very difficult one, as there is no simple formula for comparing quality work of a methodological and applied nature. We co-ordinated the work this year with Steve Goodman of the Society for Clinical Trials with whom we are having a joint conference, and the student award committees of both societies judged the papers.

The two societies worked well together, and were committed to their task. Last year (2002) an informal gathering was arranged where student winners and SCA committee members could meet and socialize. After the success of the Dijon event (organized by Bjarne Nielsen) in 2002, this event has been repeated again with success in London.

The motion for continuation of the Subcommittee was approved by the ISCB participants at the AGM.

December 2003
Emmanuel Lesaffre on Statistics in Dentistry

Emmanuel Lesaffre overviewed the terms of reference of the Subcommittee and invited interested ISCB members to join the Subcommittee, especially those from Europe since there is an under representation of European ISCB members in the Subcommittee.

Further, as first action the Subcommittee will compare the Editorial policies of Medical Journals with Dental Journals. Since the Subcommittee was established in 2003 no motion for continuation needed to be approved.

Harbajan Chadha-Boreham on Conference Organising

Harbajan Chadha-Boreham overviewed the terms of reference of the Subcommittee thereby explaining the purpose of the Subcommittee.

Since the Subcommittee was established in 2003 no motion for continuation needed to be approved.

Report on the 2002 elections for the Executive Committee

At the Dijon ISCB meeting it was decided that an electronic ballot was necessary to elect the ExCom members since there were 10 nominees for 8 vacant positions. Simon Day organised the electronic voting. There was a mistake on the email that went to Members although this was corrected and a second email sent within a few minutes. Andy Vail counted the votes. He was aware of the mistake and confirmed voting intentions with anyone who used the incorrect email. A reminder email was sent by David Warne which inadvertently went to current and past Members. Andy Vail was aware of this and checked that votes were only counted for current Members. What follows is the report by Andy Vail about the procedure followed for the election (a process that was approved by Chris Roberts and Liz Gardener).

Report: Some people sent two or more mails on the correct ballot form. A few sent one to me and one to Simon Day, who then forwarded messages. One person sent to different email addresses for me because she didn't know which was better. Several people responded to David Warne's 'remind' despite having already voted. Where two or more valid votes have been received, the first valid vote is counted, and subsequent votes discarded. David Warne's reminder also went to past members who were not eligible to vote. Since this reminder all votes received have been checked against the current membership list. Only votes from those registered as 2002 members have been counted. In total 8 candidates were elected.

Future ISCB meetings

ISCB 2004 meeting in Leiden by Hans Van Houwelingen

Hans Van Houwelingen gave a brief overview of the meeting in Leiden. In particular he overviewed the location of meeting and the social programme. He referred to the leaflet distributed during the meeting for the scientific program. ISCB members will find updated information on the meeting Web-site, linked with the Society Web site.

Cancelled ISCB 2005 meeting in Krakow by Maria-Grazia Valsecchi

Maria-Grazia Valsecchi explained that the planned meeting in Krakow was cancelled in January 2003 by Ewa Kawalec {presumably other instances were spell this way} due to serious personal reasons. Thanks for all the work she had already done and the best wishes for a good recovery go from ISCB to Ewa Kawalec.

ISCB 2005 meeting in Szeged by Julia Singer

Julia Singer announced that most probably the ISCB meeting in 2005 will be held in Szeged (Hungary) from August 22 until August 26. Further details will be given at the next ISCB meeting in Leiden.

Other business

No questions were raised from the floor. 258 ISCB members attended the AGM, as follows:

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This text discusses testing for normality in many aspects. It is organized into two large sections and a smaller one: Testing for Univariate Normality, Testing for Multivariate Normality, Additional Topics (normal mixtures, robust estimation, computational issues). It is a monograph rather than a textbook and should be easily available to practicing statisticians, if not on their bookshelves, in a nearby library. The book contains voluminous references within each chapter, tables for the use of the statistics that are proposed and a series of examples. The only quibble that I have is that the data are not supplied on disk.

Why should one test for normality? Most statistical procedures assume underlying normal distributions; if that does not hold, then, perhaps, some alternative should be tried. An immediate choice is a nonparametric procedure. For regression, the choice is not so clear. An implied question in the preceding is "can non-normality mess up an analysis?" It is definitely possible, especially with skewed distributions, for non-normality to change the size and power of a test. Thus, some strategy for dealing with this contingency is appropriate. It should provide for detecting the non-normality and then perform an analysis which satisfies the assumptions. This could be a nonparametric analysis or involve a transformation of the data or be based on a bootstrap analysis. A recent study (unpublished) shows that such procedures do not inflate the type I error and have good power under both contingencies. It is definitely inappropriate to perform a t-test and if that is not "significant" to then perform a rank sum test. This inflated the type I error from 0.05 to about 0.075. I note that testing for non-normality is similar to evaluating the safety of a new drug. One does not know what to look for until one has seen the data - and then testing for it has the flavour of a post-hoc analysis. However, planning for some general procedures seems prudent.

The introduction discusses the variety of methods of testing for non-normality and notes the text considers about 40 formal testing procedures as well as plotting methods, outlier tests and general goodness of fit tests. He notes (page 2) 'such popular tests as the Kolmogorov-Smirnov or chi-squared goodness of fit tests have power so low that they should not be seriously considered for testing normality... the performance of moment tests and the Wilk-Shapiro test is so impressive that we recommend their use in everyday practice.' Thode notes results from Geary that show the z test and tests of homogeneity of variance are disastrously affected by symmetric non-normality. For the t-test, Geary found that if the underlying distributions were symmetric, there was little distortion of the probability of rejection.

Chapter 2 (plotting) emphasizes the importance of plotting (something all readers of this review do, of course) and begins with simple plots such as histograms, stem-and-leaves, box plots and moves on to probability plotting. The book discusses plotting position for each point on the empirical frequency distribution. Most statistical programs handle this detail for the user; there are various options to consider. He lists 14 proposed options. He gives examples of Q-Q plots comparing to a standard normal distribution for six examples (normal, double exponential, uniform, exponential, mixture of two normal distributions, and an outlier example). The section on regression tests begins with a careful discussion of the Wilk-Shapiro test (WS). Manual computation of this test is difficult manually because it requires expected values of order statistics; however, statistical packages can do this directly. He then discusses tests based on correlations with the probability plot.

Chapter 3 (moments) notes that 'deviations in distribution from the normal could... be characterized by differences in the third and fourth standardized moments.' For skewness, the distribution of \( \sqrt{b_1} = m_3/m_2^{3/2} \) is asymptotically normal with mean 0 and variance \( 1/n \). He gives tables of critical values for this statistic. For kurtosis, the statistic \( b_2 = m_4/m_2^2 \) is tabulated in the book. The statistic \( b_2 \) is asymptotically normal with mean 3 and variance \( 24/n \), but needs large \( n \) before the approximation is satisfactory. Tests based on combinations of skewness and kurtosis are available (SK). The chapter concludes with discussion of several other moment tests.

Chapter 4 (other tests) includes likelihood ratio tests for various alternatives, most powerful location and scale invariant tests, U-tests, and others. Since these are less widely used, and do not appear to have advantages over the WS or SK tests, I will not discuss them further. Section 4.5 considers transformations to normality using the Box-Cox transformation. Thode notes that this requires the observations be positive (or a "starter" be added to all data to make the data positive). In practice, I've found that considering only a few values that give 'comfortable' transformations are useful. These are square root, log, inverse square root and reciprocal (in addition to the identity or no transformation).

Chapter 5 (goodness of fit tests). These include the Kolmogorov-Smirnov test, Cramer-von-Mises, Anderson-Darling, Chi-Squared test and others. Again, these tests do not seem to have any advantage over the WS and SK tests so will not be discussed here.

Chapter 6 (outliers) is not formally a normality issue in the sense that an outlier may be an experimental aberration rather than a distributional issue. The book lists five common sources of outliers: chance, failure of data generating process, a subject may be inhomogeneous with other subjects, instrument failure, measurement error (copying, data entry, etc.). Methods to cope with outliers include robust methods, removing outlier, Winsorising outliers, replacing outliers with new observations (this might be problematic for regulatory purposes), analyzing with and without the outlier.
Chapter 7 (power comparisons) compares 28 non-normality tests based on simulations for their power. ‘A test should... be based on ease or practicality of computation, and necessary tables... should be available... Regardless of the degree of knowledge concerning the distribution, it should be common practice to graphically inspect the data.’ He provides recommendations when there is knowledge of some characteristics of the alternatives, and ‘if there is no prior knowledge about the possible alternatives, then an omnibus test would be most appropriate. A joint skewness and kurtosis test such as [SK] provides high power against a wide range of alternatives... The [WS] showed relatively high power among skewed and short-tailed symmetric alternatives... and respectable power for long-tailed symmetric alternatives.’

The second major section concerns testing for multivariate normality. It has two chapters: 9) Assessing Multivariate Normality, 10) Testing for Multivariate Outliers. This situation is inherently more difficult than the univariate case, at least partly because all variables could be ‘normal’ but could be jointly non-normal. The basic recommendations include:

- Normal probability plots for each variable (without univariate non-normality there is no need to go further)
- Assess marginal non-normality (using WS or SK tests or what pleases you)
- Reduce data to fewer dimensions and test normality on that
- Direct assessment of multivariate normality. One procedure is to transform to independence by the (approximate) transformation $z_i = S^{-1/2} (x_i - m_i)$ and perform univariate tests on the transformed variables.
- Multivariate plots include the marginal plots of the original variables and using the distance measure $r^2 = (x_i - m_i)^T S^{-1} (x_i - m_i)$ which will be approximately chi-square for large $n$. Thode also recommends Beta probability plots for small sample sizes. Other methods are discussed.

Section 9.3 considers methods using marginals. An important issue is how to combine marginal skewness and kurtosis or WS tests. Generally, research has suggested transforming the SK to closer to normality and then to obtain quadratic forms that are approximately chi-squared. I have not seen such tests incorporated into statistical programs.

Methods of direct data assessment of multivariate normality are extensions of univariate methods. The problems seem to be that there are few tables, and those that exist are sparse; and the methods are computationally demanding. This section has many tests and will not be discussed in further detail.

Recommendations are:
- Examine univariate probability plots, and bivariate plots (e.g., scatter plot matrix);
- Do univariate tests of normality and adjust the critical values using the Bonferroni inequality;
- Look at tests based on dimension reduction such as the squared radii using the beta distribution;
- Use several multivariate tests, especially if there is little a priori information about the characteristics of the non-normality.

Chapter 10 discusses multivariate outliers. Preliminary assessment includes examination for marginal outliers, testing for multivariate normality, examining outliers in the principal components. The book discusses outlier methods based on distance measures in section 10.2. Robust methods have been suggested because outliers affect location, scale and correlation. In particular, influence methods are important.

The last section of the book is concerned with mixtures, robust estimation and computing issues. Sometimes the observed non-normality is due to a mixture of normal distributions rather than a single non-normal distribution. Chapter 11 covers these issues. Chapter 12 covers robust estimation of location and scale. For univariate methods, Thode notes the usual methods: M-estimators, W-estimators, L-estimators and R-estimators. He discusses adaptive estimators (D-estimators) that rely on sample characteristics. A short paragraph discusses multivariate methods. As usual, there is no single best estimator. He prefers L-estimates (linear combinations of order statistics) as being simple and having good properties. The final chapter discusses computational issues involving function minimization, estimating expected values and covariances of normal order statistics, estimating gamma parameters. Thode discusses the availability of normality testing only for SPSS. It would be useful to the field if there were indications for other programs such as SAS, JMP, S-PLUS, and Stata. I did a search in the help menu for Stata 8 and found reference to the Kolmogorov-Smirnov test, which then referred me to the Shapiro-Wilk test (the WS test in Thode’s book) and the skewness-kurtosis test. JMP referred me to quantiles, box plots. With a little searching, I found the Shapiro-Wilk test. It does not appear to have the SK test.

This book is a valuable asset to my library and provides me with a rich source for most applied concerns that I anticipate facing. I recommend this book for departments, libraries and statisticians who have questions about the normality assumption. Some other useful books would be Rupert Miller’s Beyond ANOVA (Wiley) which discusses various options when assumptions fail; and Albert Madansky’s Prescriptions for Working Statisticians (Springer-Verlag) that covers similar (but not identical) material.
You need to be mechanically minded to appreciate this book. I am not sure that many medical statisticians are such, so perhaps the book will have limited appeal to them. It is a book that, when I offered to review it, I thought might have some interesting ideas about visualizing data. But it is not a book about visualizing data, rather, as the title correctly says, it is about visualizing, mainly by mechanical analogies, models and concepts.

So the book turned out to be not what I had expected, or of especial interest to me. Nevertheless, I found it quite a fascinating book. Here you will find mechanical analogies for common summary measures of data. The arithmetic mean, for example, is discussed as the centre of gravity of a set of weights attached to a horizontal beam. The author actually prefers a different mechanical analogy in which “ideal springs” are attached to data points located on the beam and the springs joined together. The arithmetic mean emerges as the value that minimises the potential energy of the system.

The notion of springs and associated potential energy is used to describe other statistical concepts. Least squares regression is placed in this framework (Chapter 4). Generalisation of least squares, in which the author includes multidimensional scaling, are dealt with in the final Chapter 11. The method of least absolute deviation, which includes discussion of the median, is worked up in the context of mechanical models that have unit weights hanging from bits of string passing through holes in boards (Chapter 5). A hybrid mechanical model, combining features of least squares and least absolute deviations mechanical models, is used to illustrate the minimax absolute deviation method (Chapter 6).

Chapter 7 presents yet another mechanical model for the method of least median square deviations and chapter 8 is about mechanical models of metric graphs, about which I know very little. Chapter 9 deals with categorical data analysis and is different from other chapters in that, rather than mechanical models involving weights and springs, it adopts models based on liquids and gases. Potential energies of compressible gases are identified with likelihood functions of counts in categorical variables.

This book seems unlikely to appeal to practicing medical statisticians. I am not really convinced that mechanical models really help in understanding statistical concepts and models, unless you have a good understanding of mechanics, which perhaps not many statisticians have. The author suggests that clients who consult statisticians may have their understanding enhanced by descriptions of strings and springs. Perhaps. But I have myself used the centre of gravity analogy in consulting and in teaching medical statistics classes in the past and I am unconvinced that it adds much to the typical student’s or client’s understanding. However, as I have said, it is an interesting book and, for some people, perhaps engineers or physicists and the like, who want to delve into statistics, it may be helpful.
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(4) Contribute to statistical issues in regulatory guidelines | Chair/Secretary: Emmanuel Lesaffre (B), Members: Joan Hilton (USA), Carol Redmond (USA) | emmanuel.lesaffre@med.kuleuven.ac.be  
joan@biostat.ucsf.edu |
| **Education**  
iscb-education@yahoogroups.com | To organise one or two day courses on contemporary methods in clinical biostatistics which will involve one or several members as lecturers which will be presented in locations represented by the Society. Guidelines and plans of previous courses are available. | Chair/Secretary: Carol Redmond (USA), Members: Michael Schemer (A), Albert Cobos (E), Mike Campbell (UK), Shai Linn (ISR), Elisabeth Svensson (S), Nicole Close (USA), Maria Grazia Valsecchi (I) | okr3@pitt.edu  
michael.schemer@akh-wien.ac.at  
biganzoli@istitutotumori.mi.it  
eliasbianco@spadillemedimmentum.com |
| **National Groups**  
iscb-national-groups@yahoogroups.com | 1. To help those who are interested in forming a National Group through the approval process.  
2. To review the arrangements with the current National Groups, specifically regarding financial matters.  
3. To set rules and standards for funding of ISCB members of National Groups and others from countries with exchange control restrictions or barriers. | Chair/Secretary: Michael Schemer (A), Members: John Whitehead (UK), Jørgen Seldrup (F), Siem Heisterkamp (NL), Norbert Victor (D), Julia Singer (I), Ewa Kawalec (PL), Elia Biganzoli (I), Simon Day (UK), Maria Grazia Valsecchi (I) | michael.schemer@akh-wien.ac.at  
okr3@pitt.edu  
simon.day@mhra.gsi.gov.uk  
catherine.quantin@chu-dijon.fr  
grazia.valsecchi@unimib.it |
| **Statistics in Regulatory Affairs**  
iscb-reg-affi@yahoogroups.com | The subcommittee on Regulatory Affairs will review, comment upon and seek to influence the development of regulatory requirements, guidelines and other documents concerning the scientific aspects of data generation, collection, management, analysis, and reporting. In general, the subcommittee will seek out and handle all regulatory issues in the name of the Society with the approval of the President or in his absence, the Vice-President. | Chair: Jørgen Seldrup (F), Secretary: Stephen Senn (UK), Members: Helmut Schäfer (D), Karsten Schmidt (DK), Harbajan Chadha-Boreham (F), Anna Petroccione (I), Maria Grazia Valsecchi (I) | jorgen.seldrup@quintiles.com  
hsimbec@post.med.uni-marburg.de  
k8@SpadilleMeditmentum.com  
catherine.quantin@chu-dijon.fr  
grazia.valsecchi@unimib.it |
| **Student Conference Awards**  
iscb-stud-conf-award@yahoogroups.com | Student conference awards are available for registered postgraduate students to attend the annual meeting and present a paper. The Subcommittee shall receive submissions, judge them, and administer the awards. The rules are announced in a timely issue of the Newsletter. | Chair/Secretary: Marie Reilly (S), Members: Marc Buyse (B), Bruno Cesana (I), Jan Lanke (S), Maria Grazia Valsecchi (I) | Marie.Reilly@mep.ki.se  
Mark.Buyse@iddi.com  
cesana@telemacus.de  
simon.day@mhra.gsi.gov.uk  
j.r.whitehead@reading.ac.uk |

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Title & Email  
Terms of Reference  
Members  
Email addresses

How to Contact the ISCB Subcommittees (2004)
The International Society for Clinical Biostatistics (ISCB) was founded in 1978 to stimulate research into the principles and methodology used in the design and analysis of clinical research and to increase the relevance of statistical theory to the real world of clinical medicine.

The ISCB organises an annual scientific meeting which members and non-members are able to attend. The main objective of the annual scientific meetings is to create an opportunity for the exchange of knowledge, experience and ideas among clinicians, statisticians and members of other disciplines, such as epidemiologists, clinical chemists and clinical pharmacologists, working or interested in, the field of clinical biostatistics.

The scientific meetings cover a broad spectrum of biostatistical interests and regularly include sessions on the design and analysis of clinical trials, epidemiology and statistical methodology, as well as from time to time considering more specialist issues such as, for example, education of biometricians and biometrics users, pharmacokinetics, medical data-bases and pharmaco-epidemiology. Each meeting includes a mini-symposium devoted to a particular medical or statistical field. Recent topics have included Environmental epidemiology, Assessment of drug risks, Statistical challenges in paediatric research, Cancer genetics, Human fertility and fecundity, and Emerging issues in clinical trial data monitoring.

Meetings in recent years have been held in Boston (1997), Dundee (1998), Heidelberg (1999), Trento (2000), Stockholm (2001), Dijon (2002) and London (2003). A selection of talks at the meetings, for which papers are submitted for review and which are eventually accepted, are published in Statistics in Medicine. The ISCB benefits from a special journal concession from John Wiley & Sons Limited, the publishers of Statistics in Medicine, so that members are able to subscribe to the journal at a preferential rate.

The ISCB also organises courses to cover particular statistical topics. These are run to precede or follow on from the annual scientific meeting and are given by the foremost researchers in the field. Recent courses have included Developing and validating prediction models, Mapping and risk assessment, Statistical methods in genomics and computational biology, Introduction to frailty models, Developing and validating clinical prediction models, Design and analysis of studies with incomplete data, Smoothing and generalised additive models, Event history analysis, Introduction to genetic epidemiology, Adaptive and sequential procedures for clinical trials, Methods of interval censored data, Issues and controversies in data analysis, Sequential Monitoring: Practical implementation of sequential designs for phase III clinical trials, Coping with missing outcome data, Essentials of clinical trials, Statistical validation of surrogate endpoints in clinical trials.

Applications for membership should be sent to:
ISCB Permanent Office,
P.O. Box 130,
Datavej 24,
DK-3460 Birkeroed,
Denmark

Tel. +45 4567 2279,  Fax +45 7022 1571
email: office@iscb.info  www: http://www.iscb.info

The composition of the Executive Committee (ExCom) for 2004 is as follows:

**Officers:**
- President: Maria Grazia Valsecchi (I),
- Vice-President: John Whitehead (UK),
- Secretary: Emmanuel Lesaffre (B),
- Treasurer: Norbert Victor (D).

**Members:**
- News Editor: David W. Warne (CH),
- Webmaster: Silvia Codony (DK),
- Elia Biganzoli (I), Harbajan Chadha-Boreham (F), Simon Day (UK), Stephen Evans (UK), Sien Heisterkamp (NL), Bjarne Nielsen (DK), Carol Redmond (USA), Julia Singer (H), Elisabeth Svensson (S), and Koos Zwinderman (NL).

The annual general meeting of the ISCB is organised to coincide with the scientific meeting. Membership of the Society is drawn from more than 40 countries worldwide and the number of members is nearly 800.

The ISCB also has special Subcommittees dealing with particular aspects of biostatistics.

The Society publishes a Newsletter 2 or 3 times a year. The ISCB News editor is David W. Warne, Chemin Frank-Thomas 40, CH-1208 Geneva, Switzerland. Items for inclusion in the Newsletter should be sent to him via email to:

david_w_warne@bluewin.ch

Membership of the Society is open to all with an interest in biostatistics. The current annual (to 31 December 2004) Ordinary membership fee is €40. The Full-time Student Membership fee is €20.
INTERNATIONAL SOCIETY FOR CLINICAL BIOSTATISTICS
2004 Membership Subscription

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Please provide your email address as it will be used to send you the ISCB News in the future.

SUBSCRIPTION:
Ordinary membership of ISCB (to 31 December 2004): Euros (EUR) 40.00
Full-time Student Membership of ISCB (to 31 December 2004): Euros (EUR) 20.00
(students should provide a letter from their supervisor or head of department)

Have you previously been a member of ISCB? Yes No

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For the latest conference info, see: http://www.cbs.nl/isi/calendar.htm