



International Society for Clinical Biostatistics

News

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Editor: David W. Warne

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Editorial

The 30th ISCB conference, which took place in Prague in the Czech Republic, was another great success, scientifically, socially and financially. Thanks to all the people involved in the preparation, the LOC, SPC and all those who took part by giving presentations and posters. Zdenek Valenta in this News looks back at the highlights, including the 30th Anniversary lectures by John Whitehead and Stephen Senn, our 2 new honorary ISCB members.

For the AGM, reports from the President, Treasurer and all the Subcommittees were available in writing in Prague, and are included in the AGM report in this News. Have a look at the excellent work these groups are doing and also the plans for future meetings.

Work has been progressing well for next year's conference in Montpellier, France, and the conferences for 2011-14 are being lined up. Please see the article about Montpellier in this News and the conference brochure.

Thanks to the contributors to this News: Jean-Pierre Daurès and Christel Castelli, Zdenek Valenta, Norbert Victor, Emmanuel Lesaffre, Sylvain Larroque and the book reviewers, and the representatives of the 3 National Groups.

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 Regulatory Affairs: Christoph Gerlinger (D)
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ISCB Membership

Welcome to the 257 new members who joined ISCB by attending ISCB30 in Prague. Please renew your membership!

*=host of	Conference	end 89	end 92	Dec 93	Dec 94	Dec 95	Dec 96	Dec 97	Dec 98	Dec 99	Nov 00	Nov 01	Dec 02	Nov 03	Nov 04	Nov 05	Nov 06	Nov 07	Dec 08	May 09	Nov 09
	Total	261	596	715	698	725	702	685	729	818	797	837	825	756	758	620	808	800	921	458	862
	# Countries	23	32	32	31	33	34	37	37	41	40	45	41	40	38	39	40	41	42	31	39
1.	UK	50	90	176*	120	144	121	128	169*	135	151	153	141	190*	140	109	133	117	114	52	124
2.	Germany	30	67	75	84	71	78	72	70	186*	90	87	77	61	57	51	73	48	59	31	72
3.	USA	18	45	40	39	41	40	79*	66	76	77	89	78	75	57	51	67	62	74	28	67
4.	Poland [NatGrp]		11	11	24	24	30	21	19	26	34	37	41	41	43	40	49	54	62	63	66
5.	Denmark	4	58*	38	31	30	32	26	35	38	39	36	46	41	37	37	40	34	154*	38	54
6.	Netherlands	14*	30	38	33	36	29	31	39	35	33	38	39	33	87*	35	44	41	39	20	49
7.	France	30	52	62	50	73	67	52	52	49	53	37	93*	31	41	30	57	41	49	13	49
8.	Hungary [NatGrp]	1	21	17	18	19	25*	27	29	29	33	34	41	48	42	38*	50	44	43	43	44
9.	Czech Rep. [NatGrp]			1	1	1	1	1	1	2	2	1	1	1	1	3	17	36	28	30*	44*
10.	Romania						2			4	1	1	1	19	21	30	28	30	31	36	36
11.	Belgium	13	22	27	30	30	32	35	29	25	33	36	33	23	27	24	23	32	33	15	33
12.	Switzerland	14	25	22	80*	33	29	24	25	23	18	23	26	22	23	23	55*	28	26	14	28
13.	Japan	2	6	7	5	7	4	10	13	20	12	11	10	10	10	17	17	27	20	7	26
14.	Norway	13	18	25	22	12	18	10	10	11	10	16	16	12	14	12	13	12	19	7	21
15.	Sweden	23	51	53	54	58	64	51	45	38	44	88*	50	36	34	24	23	19	27	7	19
16.	Canada	6	12	14	14	11	13	15	14	9	9	10	14	16	8	12	12	19	22	9	18
17.	Austria	4	9	11	13	11	16	13	11	15	18	15	13	16	17	15	14	16	17	8	15
18.	Spain	10	12	18	12	46*	23	14	16	12	11	11	8	7	15	5	9	8	5	1	14
19.	Australia	6	9	11	6	9	8	11	9	10	12	8	9	14	8	6	11	11	10	7	13
20.	Italy	16	33	37	32	32	33	26	33	26	63*	29	25	15	25	15	23	24	20	6	10
21.	Finland	2	7	7	9	9	9	7	5	10	9	18	11	7	11	10	6	8	8	6	9
22.	Greece		1	1	1				1	1	3	1	6	1	2	2	3	50*	5	2	7
23.	Taiwan										1	1	1	1	1	1			3	1	7
24.	South Korea					3		1						1				1	6		6
25.	South Africa		1	4	1	3	2	2	2	2	3	3	3	3	3	3	3	2	2	2	5
26.	India		1	1	1	1	1	1	1	1	2	1	2	2	3	2	2	3	4	3	4
27.	Slovenia		1	2	3	2	1	1	3	2	1	2	1	2	3	3	4	5	5	2	4
28.	Slovakia												1			1	2	2	2	2	2
29.	Malaysia					2	1	2	2	1	1	1	1	1	3	3	2	1	1	2	2
30.	New Zealand		1		1		2	1	2	2	2	3	3	3	1	2	2	2	5	1	2
31.	Turkey		1	1						1				1	2	2	3	4	7		2
32.	Portugal	1	3	5	2	2	2	2	5	5	3	4	3	3	1	1	1	2	6		2
33.	Iran						1	1					1	1	4	1	3	5	1		2
34.	Brazil					2						1							1	1	1
35.	Cuba								2	2	2	2	2		2	1		1	1	1	1
36.	Israel	1	3	4	4	4	4	3	3	4	10	13	10	7	8	3	4	2	2		1
37.	Indonesia						1														1
38.	Pakistan								1	1	1										1
39.	Kenya		1	1																	1
40.	Singapore							3	6	4	5	8	5	7	2	4	6	2	4		
41.	Ireland	1	2	3	4	3	4	4	2	3	2	3		1	1				2		
42.	Russia					1	3	3	3	2	2	1	4	3	2	1	1	1	1		
43.	Sri Lanka																1	1	1		
44.	Bangladesh																		1		
45.	Mexico						1	1	1	1	1	1	2	2	2	1	1		1		
46.	Luxembourg																		1		
47.	Estonia											2		1		1	1	1			
48.	United Arab Emirates															1			1		
49.	Chile																	1			
50.	Thailand		1	1		1	1	2	1	1	2	2	2				3				
51.	Saudi Arabia											1					1				
52.	Malawi												1	1	1						
53.	Colombia							1	1		1		1								
54.	China		1	1	2	3	3	3	3	3	3	3	2								
55.	Croatia									1	1		1								
56.	Gambia												1								
57.	Lithuania											2									
58.	Argentina											1									
59.	Kuwait	1											1								
60.	Sudan												1								
61.	Ukraine									1		1									
62.	Egypt											1									
63.	Philippines									1											
64.	Zimbabwe				1																
65.	Oman	1																			

From Norbert Victor

The first year of my presidency is almost over); it passed incredibly fast. But in this period, there have been many successful ISCB activities. Regarding events and activities prior to our conference in Prague, I can refer to my report given in the AGM, which can be found as part of the AGM minutes contained in this issue of our Newsletter.

ISCB30 Prague was a huge success: we enjoyed 460 participants, a large financial surplus, an exciting scientific programme, well-attended courses and mini-symposia, many productive administrative meetings and an attractive social programme. I feel obliged to repeat here my expressions of thanks pronounced during the conference: Zdenek Valenta and the whole team around him did an excellent job and made the Prague conference unforgettable in the word's best sense. Let me recapitulate some highlights:

- The excellent weather during the whole conference allowed us to enjoy the beauty of the "Golden City" of Prague.
- The exciting and intensively discussed Keynote of Marc Buyse, the President's Invited Speaker: On trial endpoints that combine clinical relevance and statistical efficiency. The paper on which Marc's speech was based will appear in the congress special issue of Statistics in Medicine.
- The Honorary Memberships attributed by the ExCom and the AGM to Stephen Senn and John Whitehead. The laudations are included in the AGM minutes.
- The celebration events for ISCB's 30th anniversary:
 - The presentations on ISCB's history, by Stephen Senn and John Whitehead, in an informative and reminiscent entertainment.
 - The excellent exhibition about history, development and congresses of ISCB, prepared and coordinated by our Secretary, David Warne. Many colleagues, among others (Elisabeth Svensson, Nancy Geller, Lutz Edler, Maria Viskaduraki, Shagufta Sultan, Daniela Casula, Marc Fourneau, Roshini, Stephen Senn and David W. Warne), contributed pictures and other material to this collection, which will now form the foundation of the ISCB archives.

Since Prague, the following activities are noteworthy:

- The preparation of ISCB31 in Montpellier made great progress. All invited speakers, including the President's Invited Speaker Norman Breslow, confirmed their unqualified acceptance of the invitations, an excellent website (www.ISCB2010.info) was finalized and the canvassing for sponsors is encouraging (see also the report and invitation of Jean-Pierre Daurès in this issue).
- The Romanian National Group is on the way of being reformed, owing to impressive activities of Anca Vitcu from the University of Iași.
- A large number of colleagues registered for the course on "Prognostic Modelling" organised by Catherine Quantin in Dijon (France) in November 2009.
- During their usual quarterly teleconference, the officers finalised the contract with the National Research Council Canada as conference service office for ISCB32 in Ottawa, we set up a working group for drafting guidelines for "joint meetings", we approved the SC reports, and we discussed new ways of presenting our Awards and the handling of SC reports in our AGM.

I hope this list of activities shows that ISCB is really a "living" scientific Society (with 862 members in November 2009), permanently working on improvements regarding effectiveness, visibility and acceptance of our profession Biostatistics. Let me – in closing – say thank you to all of you who contributed this year to ISCB activities and its successes. I wish you all a Merry Christmas and a happy and successful New Year!



Stephen Senn and John Whitehead
Honorary ISCB Members 2009

“Biostatistics and Clinical research: A Symbiosis”: A common Invited Paper Meeting of ISCB and ISI at the 57th ISI Session, 16-22 August 2009, Durban (South Africa)

From Norbert Victor

The International Statistical Institute (ISI) is one of the oldest international scientific societies (founded 1853) recruiting its members only by election. Its bi-annual Sessions are worldwide the largest statistical congresses. ISI considers itself as the umbrella organisation of the whole statistical profession, but in its membership official and mathematical statisticians are over-represented and biostatisticians are under-represented.

After a request from the ISI Programme Committee for a common Invited Paper Meeting with “sister societies” in 2007, the ISCB officers proposed the topic “Biostatistics and Clinical research: A Symbiosis”; the ISI accepted and the ISCB President at that time asked me to organize the session. In planning the session, my objective was to give Biostatistics the right place and appreciation in the entire statistical discipline, and to give biostatisticians the proper position in the professional statistical community. Furthermore, it should be demonstrated that efficient progress in Clinical Research is possible only with statistics, and that, on the other hand, the development of biostatistics almost completely was driven by striving for methods and models appropriate to problems of medical research. It should be underlined that there is a real symbiosis between biostatistics and clinical research.

I asked Emmanuel Lesaffre to give a report on the development of ISCB and on its contribution to advances in clinical research. In the paper (written together with Harbajan Chadha-Boreham) the specificity of biostatistics and the need of a Scientific Society focussing on this area were clearly demonstrated. The authors reported also ISCB's activities for improvements in clinical research, and they described achievements which have been made possible by biostatistics alone.

In the second paper, Lutz Edler and collaborators emphasised that clinical research with statistical methods is feasible only with team work: Cooperation of biostatisticians with clinical researchers is crucial. He contrasted two ways of organising the statistical support in medical research institutions: establishing a biostatistics unit within these institutions or consulting by independent statisticians from

outside. He reported the good experiences with the first of those models realized at the German Cancer Research Centre (dkfz), and discussed the advantages of this cooperation model.

As third lecturer, Rumana Omar dealt with the difficult dissemination of statistics in the medical scientific community. Rumana outlined difficulties as well as ways to teach biostatistical principles and methods to health researchers. She clearly demonstrated that cooperation of biostatisticians and health researchers, especially clinicians, can only be successful if biostatistical principles are communicated to (and understood by) those.

In the fourth lecture it was the task of Aeilko H. (Koos) Zwinderman to show actual challenges for biostatistics and to outline that clinical biostatistics has promising perspectives in the future. He spoke about “Sparse Canonical Correlation Analysis for Identifying, Connecting and Completing Gene-Expression Networks” showing that our methodology must be permanently adapted to the requirements of medical research problems. This paper demonstrated clearly how big the methodological challenges in molecular genetic investigations are: In genome wide gene-expression studies there might be easily tens of thousands of new candidates, causing huge statistical multiple testing problems. Koos presented the application of recently developed penalized canonical correlation analysis to identify the correct genes from a large set of candidates.

As invited discussant, Geert Molenberghs (chairman of the ISI Life Science Committee) emphasized the importance and specificity of biostatistics. He discussed especially different new models of cooperation between biostatisticians and medical researchers. His conclusion was: Improvement of this cooperation will be the crucial point for further advances in medical research. The subsequent discussion from the floor showed that – by this session – the interest in biostatistics was stimulated within the ISI family.

Some of the presentations and papers are (or soon will be) available on the congress website: <http://www.statssa.gov.za/isi2009/ScientificProgramme/Ipms.aspx>

From Jean-Pierre Daurès and Christel Castelli

In 1990, Claude Chastang helped organise the annual conference of the International Society for Clinical Biostatistics (ISCB) in Nîmes. Twenty years later, we are honoured to organize and dedicate to his memory the 31st annual ISCB congress, to be held in Montpellier, from 29 August to 2 September 2010.

The local organising committee, supported by the Nîmes University Hospital, the University of Montpellier I, the Montpellier-Nîmes School of Medicine, and assisted by Alpha Congrès, has chosen the National School of Agronomy at Montpellier as the site for this year's congress. This pleasant and functional site will be made available to you with all the facilities necessary to insure that this event will take place in a professional and enjoyable manner.

We have also added a new aspect to the organisation of this year's congress. The session on vaccines has been expanded, and will take place all day on Sunday, the first day of the congress. This subject is attracting a great deal of current interest at various social and professional levels. Its many facets, including modelling, evaluating efficacy, and risks, will be considered with the utmost rigour.

Several courses are also proposed in parallel with the session on the first day of the congress: Stijn Vansteelandt and Vanessa Didelez from the Universities of Ghent and Bristol have proposed a day-long course on "Causal Inference." Deborah Ashby from the University of London will lead a course on "Bayesian Statistics for Clinical Trials and Drug Regulation". David Clayton from the University of Cambridge has proposed a course entitled "Analysis of genome-wide association studies in R." Finally, Patrick J. Heagerty from the University of Washington will lead a half-day course on "Inference and Prediction using longitudinal data."

The official conference will begin on Monday 30 August 2010, and the invited sessions will be spread over the entire week. At 1900 on Monday evening, a welcome cocktail will be served in the Honour Court of the oldest school of Medicine in Europe, where participants will be received by Jacques Bringer, Dean of the Montpellier-Nîmes School of Medicine.

The ISCB President's invited speakers for 2010 will be Norman Breslow from the University of Washington.

The Scientific Programme Committee has not only proposed traditional themes, but several additional innovative ones:

- "Novel approaches to clinical trials: New developments in Bayesian adaptive trials," organised by Dave Dunson
- "New statistical methods for pharmaco-epidemiology," organised by Catherine Quantin
- "Analysis of complex data: Competing risks and multi-state models," organised by Helene Jacqmin-Gadda and Jan Beyersmann
- "Development of risk prediction models," organised by Thomas Gerds
- "Use of genetic data: multiple testing," organised by Jelle Goeman
- "Mixed models," organised by France Mentré

Thursday morning will be devoted to a mini-symposium on a public health problem for society: modelling terminal renal insufficiency; dialysis and renal transplantation.

The call for abstracts for the 31st annual conference of the ISCB is scheduled for 15 December 2009. The Society will again sponsor several graduate student awards and scientist awards available for the researchers from targeted countries. All relevant information may be found on the website.

In addition to the scientific content of ISCB 31, the organisers have taken great pleasure in preparing an attractive social programme for attendees and their accompanying persons. We offer you the opportunity to visit one of the following four sites: historic Montpellier; the medieval fortified town of Aigues Mortes; the UNESCO world heritage site, Saint Guilhem le Désert; a visit to the city of Arles, including the Roman arena and theatre, the Sainte Tropicisme Convent, the underground city, the "Alyscams", the Van Gogh museum, and the Rhône museum, where the only bust of Cesar, contemporary to his lifetime, is on display.

All the members of the LOC and SPC are happy to invite you to participate in the 31st conference of the International Society for Clinical Biostatistics.

ISCB31 Montpellier 2010: Conference Awards for Scientists (CAS)

From Julia Singer

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 31st ISCB Meeting in Montpellier, France, from 29 August – 2 September 2010. Up to six such awards will be granted.

Selection will be made on the basis of submission of an abstract together with the poster to be displayed or the slides for an oral presentation. Judges will be looking for contributions describing new statistical methods and illustrating their implementation in medical research, or presenting the results of medical studies which involve novel and interesting applications of biostatistics. It is the blend of statistics and medical research that is being sought: contributions presenting only new theory or only study results will not be selected.

An award consists of free accommodation, a short course and registration paid by ISCB. First-time

attendants can apply for the support of travel fees as well. Up to one travel fee support per year will be granted. Full details of the scheme are given below. Scientists should submit the application form, the abstract of the poster/oral presentation and the complete poster or slideshow of the presentation, respectively, to:

Julia Singer
Baxter Innovations GmbH
Global Clinical Biostatistics
IZD Tower
Wagramer Strasse 17-19
A-1220 Vienna
AUSTRIA
Tel: +43 1 20100 3587
Fax: +43 1 20100 534
Email: julia_singer@baxter.com

The closing date for application is 15 March 2010.

ISCB31 Montpellier 2010: Student Conference Awards (SCA)

From KyungMann Kim

The Student Conference Awards are available for registered postgraduate students to attend and present a paper at the 31st ISCB Meeting in Montpellier, France, during 29 August–2 September 2010. Three awards will be made.

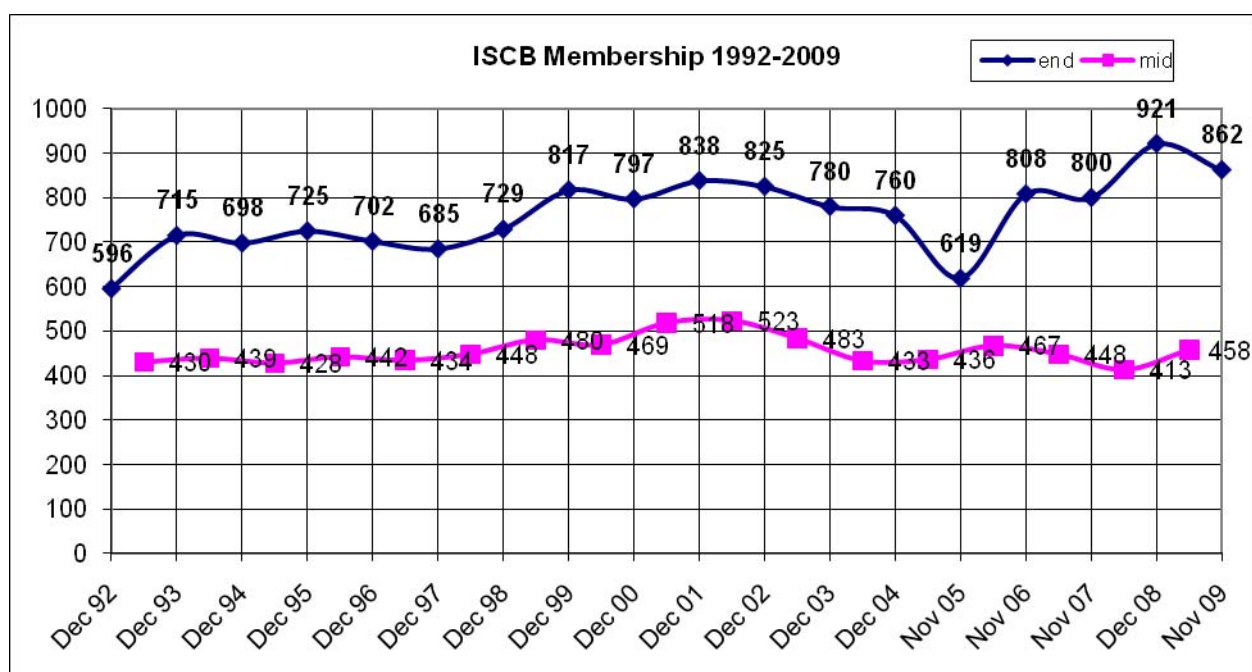
Selection will be made based on an abstract and a summary of a paper to be presented, which should illustrate the application of statistical methodology to clinical or epidemiological research. Results of particular studies are of interest only if the analysis has methodological implications or shows a novel and interesting application of biostatistics.

Applications should be sent to:

KyungMann Kim
Department of Biostatistics and Medical Informatics
University of Wisconsin School of Medicine and Public Health
600 Highland Ave, Bx 4675
Madison, WI 57392
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Tel: +1 (608) 265-6380
FAX: +1 (608) 265-5579
Email: kmkim@biostat.wisc.edu

The closing date for application is 15 March 2010.

ISCB Membership – 1992-2009



ISCB30 Prague 2009: AGM Report

From David W. Warne (ISCB Secretary)

ISCB Annual General Meeting in Prague at ISCB30: Minutes

Wed 26 Aug 2009: 12.15-~13.30

PARTICIPANTS

President:	Norbert Victor (Germany)	Vice-President:	Harbajan Chadha-Boreham (Switzerland)
Treasurer:	Koos Zwinderman (Netherlands)	Secretary:	David W. Warne (Switzerland)

All ISCB Members present in Prague were invited to attend.

In fact, a total of about 54 members attended which made the meeting quorate [Constitution (9.08)]: The Officers plus Pascoe (Australia), Schemper, Singer (Austria), Buyse (Belgium), Abrahamowicz, Ramsay (Canada), Jimenez (Cuba), Valenta (Czech Republic), Bodin (Denmark), Castelli, Denis, Ducharme, Foucher, Ladret, Quantin, Reynes, Sabatier, Thalabard (France), Binder, Edler, Faldum, Gerlinger, Grambauer, Hinke, Mansmann, Sauerbrei (Germany), Sypsa (Greece), Boda, Lang (Hungary), Decarli, Klersy, Valsecchi (Italy), Lesaffre, Nauta, Stijnen, van der Tweel, van Putten (Netherlands), Eide (Norway), Katina (Slovakia), Werner (South Africa), Svensson (Sweden), Rosenkranz, (Switzerland), Billingham, Metcalfe, Omar, Senn, Whitehead A, Whitehead J (UK), Dunning, Kim (USA).

For the first time, a printed document with the agenda, President's and Treasurer's and SC Reports was available to members at the Registration Desk (from Tuesday morning) and was handed out at the beginning of the meeting. This allowed the presentations to be shorter than normal. Unless stated otherwise, the reports below summarise each agenda item. Any discussion is added afterwards.

AGENDA items:

1.	President's Report -	Norbert Victor
2.	Treasurer's Report -	Koos Zwinderman
3.	Subcommittee Reports (NB reports are as they were prepared pre-Prague)	
1.	Presentation of CAS certificates	Julia Singer + 6 winners
2.	Presentation of SCA certificates	KyungMann Kim + 3 winners
3.	Discussion and motion for continuation of SCs:	David W. Warne
	3.1 National Groups -	Julia Singer
	3.2 Student Conference Awards -	KyungMann Kim
	3.3 Conference Organising -	Harbajan Chadha-Boreham
	3.4 Education -	Rumana Omar
	3.5 Membership -	Emmanuel Lesaffre
	3.6 Statistics in Regulatory Affairs -	Christoph Gerlinger
	3.7 Vaccines -	Jos Nauta
4.	3.8 Epidemiology - New SC	Harbajan Chadha-Boreham
4.	Future meetings	
1.	2010 Montpellier [31] update -	Gilles Ducharme
2.	2011 Ottawa [32] full proposal awaited -	Tim Ramsay
3.	News about 2012 Bergen [33], - 2013 Vienna [34], 2014+ meetings	Harbajan Chadha-Boreham
5.	Honorary Memberships	Norbert Victor
6.	Any Other Business	David W. Warne

1. PRESIDENT'S REPORT – NORBERT VICTOR

It was a special pleasure for me to start my term as President of ISCB with the year of its 30th Anniversary. In these 30 years, ISCB became a well-respected and influential scientific society: the worldwide most important society for Biostatistics. Some celebrations already took place during the ongoing conference.

It is also a pleasure to serve as President after the very successful term of Emmanuel Lesaffre, who performed an enormous amount of successful work, so that I can make use of a well functioning organisational structure. With nine years' experience as an ExCom member, I am confident that the positive development of our society can be continued based on the achievements established by my predecessors.

I deeply want to express my thanks to Emmanuel, but also to the other Officers and all Ordinary Members of the ExCom. Thanks go also to the Nomination Committee, chaired by John Whitehead, and to the Ballot Committee, chaired by Vana Sypsa. Our Treasurer, Koos Zwinderman, looks back on a successful period: The Society's financial situation has much improved and can now be considered as very healthy (see Treasurer's Report). I am especially thankful for his acceptance of a second term in this hard job. Harbajan Chadha-Boreham finished four years of service as Secretary; she set up very high standards of reporting and supported efficiently the work of the Officers and the ExCom, in addition to chairing the Conference Organization Subcommittee (SC) and to her activities in other SCs. Last year, she was elected Vice President and, with her long experience, she is well prepared to succeed me in 2011 as President. As new Secretary, David W. Warne was elected; he started his term with much enthusiasm and with many new ideas. As a further result of last year's election, the ExCom welcomes six new members: Lucinda Billingham, Krisztina Boda, Giota Touloumi, Lutz Edler, Ulrich Mansmann and Jean-Christophe Thalabard; Adriano Decarli and KyungMann Kim will serve for a second term. I feel honoured to chair the new ExCom and in particular the Officers.

In monitoring the Society, I continued (and will continue in the future) the tradition of Officers' quarterly telephone conferences, installed by John Whitehead and perfected by Emmanuel Lesaffre. This custom proved to be a very efficient way to interact and to steer the evaluations in our Society and its outside relations. By initiative of the new Secretary, after each telephone conference, all ExCom members receive a short report containing the decisions and the main discussion points of the teleconference.

For the second time, the Officers proposed to make use of the possibility to honour members according article 4.03 of our Constitution. We proposed to award two of our colleagues with the Honorary Membership: Stephen Senn and John Whitehead gave service of outstanding value and exceptional long duration to ISCB. This proposal has been supported unanimously by the ExCom and needs to be approved by the majority of the AGM. We are confident it will be passed.

The Subcommittee Chairs sent all written reports (containing lists of actual members and functions), which are joint to this report. All reports have been presented and discussed in the ExCom, which proposed unanimously the continuation of all SCs. According our constitution, it is the right of the AGM to vote on the demands of continuation, and we will do this during a later item of today's agenda. In view of the previously distributed SC reports, I can be short (questions will be answered by the SC Chairs under the following topic 3): As in the past, all SCs have been quite busy. The new Vaccines SC has been especially active; it holds monthly telephone conferences, implemented its own website and is organising in Prague its second mini-symposium. Furthermore, I would like to mention the remarkable increase of membership in the Regulatory Affairs SC, which is now back to its old power, and the activities of the Task Force Epidemiology under the leadership of Vana Sypsa. The task force submitted a proposal to the ExCom to transform it in a regular SC; the ExCom voted in favour and nominated Vana as first chair of the new SC. As every year in the past, the Education SC sponsored a course ("Generalized Mixed Models") which took place in Krakow (Poland) and was attended by more than 30 scientists. Also, for the first time, the SC will organize a workshop that is not a course in a target country. The workshop on "Prognostic Modelling" was Catherine Quantin's initiative and will be held in Dijon (France) in November of this year. The SC Chairs Julia Singer (National Groups) and Rumana Omar (Education) have accepted their nomination for a second term, and – as successor of the SC's initiator, Andrew Dunning, – Jos Nauta was nominated as chair of the SC Vaccines.

In all its activities, the Society has been assisted by the Permanent Office, located in Copenhagen. In particular, I wish to thank Rita Schou and Bjarne Bodin for their commitment. In view of the very efficient manner of support and of the very smooth cooperation, we decided to prolong the contract with the Copenhagen team.

Mentioning Copenhagen reminds me of last year's conference: ISCB29 was a great success: scientifically, socially and financially. The Treasurer's report shows that with the surplus of Copenhagen, our Society reached the financial aim set up four years ago. We are thankful to Bjarne Bodin, the whole Local Organising Committee and the Scientific Programme Committee for their excellent work making the Copenhagen congress unforgettable.

This year's conference is attended again by about 466 participants. About 170 papers are presented, more than 130 posters are exhibited, 4 well-attended courses took place on Sunday, and tomorrow 2 mini-symposia are organised. Zdenek Valenta with his local team, and the SPC, chaired by Geert Molenberghs, have done their utmost to make ISCB30 Prague a big success and a further highlight in the row of splendid ISCB conferences. Zdenek gave a detailed report in the ExCom session; he is expecting a considerable profit. We have to be very thankful to everyone, before and behind the scenes, who contributed to the success of this congress.

Considering our annual meetings, the future looks great:

- The preparations for Montpellier 2010 are well advanced: the LOC has worked hard to shape the congress, negotiations for sponsoring are promising and the SPC under the chairmanship of Emmanuel Lesaffre designed a very interesting scientific programme. Jean-Pierre Daurès gave a detailed report in the ExCom and Gilles Ducharme will present the congress plans later on and show us pictures of Montpellier.

- Ottawa 2011 is on the rails; the proposal was presented by Tim Ramsay in the ExCom, and the ExCom decided unanimously to hold ISCB32 in Ottawa. Tim will give a short presentation of the plans for Ottawa 2011 after the Montpellier presentation.

- Furthermore under the topic "congresses", Harbajan will give some information on congress ideas for the further future. For 2012 we plan to accept an invitation of Geir E. Eide to Bergen (Norway); Geir reported on the very interesting plans in Bergen in the ExCom meeting. As for 2013, we have a concrete candidate: we received a letter of intent from Michael Schemper to organize ISCB34 in Vienna in 2013.

Hence the future of our Society looks bright: with four successful meetings in a row, with promising conferences in the future and a membership of over 700, we can look optimistically to the future. But regarding the general trends of decreasing membership in scientific societies and considering the fact that more than half of our membership undergoes an unforeseeable fluctuation (member only by participation in our yearly meetings) does not allow us to be too relaxed. We should continue to make ISCB and its congresses "the" forum where biostatisticians, clinical and epidemiological researchers can interact and exchange their ideas. Furthermore, let us strive to a rejuvenation of our membership by trying to attract more young statisticians, e.g. by offering them active roles in our society.

Norbert Victor, ISCB President, Prague, August 2009

- Discussion: After the President's summary of his report, there were no comments.

2. TREASURER'S REPORT – KOOS ZWINDERMAN

The financial situation of the ISCB is sound. The financial report over the year 2008 was published in the ISCB News in June 2009. In summary, there was a surplus in 2008 of € 88,566, totally due to the successful Copenhagen conference. This means that equity of the Society was € 210,541 at the start of 2009.

The last six years, the Society's financial policy has been to bring the equity up to € 150,000. This number corresponded roughly with the Society's liability when the yearly conference has to be cancelled, and leaves then enough capital for the Society to organize a new conference in the next year. This goal has now been reached.

The latest budgets of the Society have already been fixed to break even, and I propose to continue with a break-even budget for the year 2010: see below. In comparison with the budget of 2009, there is a need to increase the costs of the Permanent Office with the inflation rate in Denmark, and I propose to increase the conference surplus to € 20,000 to cover this. This seems realistic because the proposed budgets of the Montpellier and Ottawa conferences are expecting such a surplus.

With respect to the expenses in 2008 it is clear that we expended more on the officers/ExCom and award items than originally budgeted. With respect to the awards this can be explained by the fact that extra prizes were awarded. With respect to the officers/ExCom item it is not clear what the reason is for this difference, but I suspect that the Copenhagen accommodation was relatively expensive. With respect to both I suggest not to change the budget items.

The current financial situation allows us to review the economy measures taken by the Society in 2002.

1. Payment for their own conference dinner by the Officers.
2. Limitation to 3 Student Award winners.
3. Limitation to 6 sponsored Scientists in future years.
4. Limitation to one ISCB sponsored course during the coming years.
5. The Officers will register for mid-priced hotels, and have reasonable travel expenses.
6. Limit the number of Newsletters circulated each year to two.

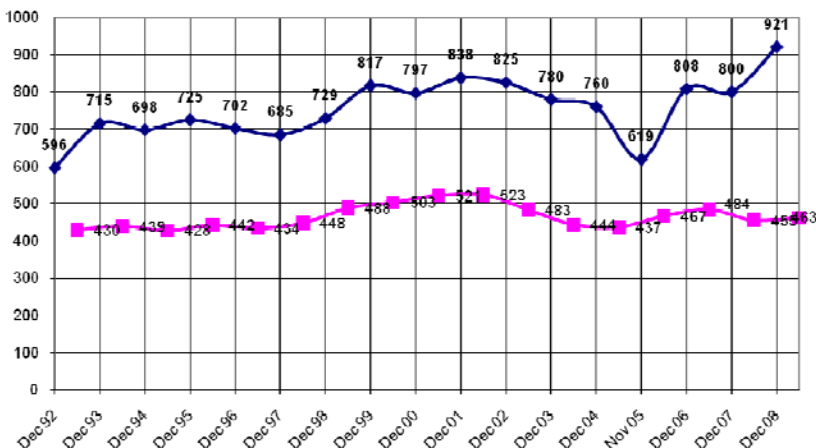
Change of any of these measures will have structural consequences for the Society's budget, and it is unclear whether the coming conferences can guarantee sufficient surplus. I am therefore not in favour of changing the economy measures. But there is sufficient equity for increasing the number of awards, which previous Annual General Meetings has asked for, or for financing new initiatives (extra courses, more newsletters, new conferences...). I suggest to do this on a temporary (i.e. year-by-year) basis only, and to finance these from the Society's surplus equity (i.e. 50,000 – 60,000 €, currently).

AH Zwinderman, ISCB Treasurer, Amsterdam, 23 July 2009

Proposal for the ISCB Budget 2010

	Budget 2010	Budget 2009	Results 2008
INCOME			
Membership fees	21000	21000	26580
Conference surplus	20000	19000	111201
Advertising+Interest	5000	5000	2581
Total	46000	45000	140362
EXPENSES			
Office	16000	15000	16294
Officers and ExCom	7000	7000	11154
Awards	8000	8000	11085
President's invited speaker	2000	2000	425
Workshops	2000	2000	2000
Newsletter	7000	7000	7923
Miscellaneous	3000	3000	2914
Representation at sister-conferences	1000	1000	0
Total	46000	45000	51795

ISCB Membership



- Discussion: The Treasurer gave a short presentation and added that the Budget will still be set to break even. Koos also proposed to let the membership fees unchanged. The Society's Equity risks to continue increasing and so the SCs will discuss with the ExCom how best to use the extra money. The report and proposals were approved unanimously.

3.REPORTS OF THE SCS

3.1 National Groups - Julia Singer

Annual Report of Subcommittee	National Groups
Report Date	23/Jun/2009
Report Author(s)	Julia Singer
Subcommittee Start date	Aug/1996
Chair	1. Julia Singer (Austria) since Jan/2006
Members	2. John Whitehead (UK) since mon/yyyy 3. Krista Fischer (EST) since mon/yyyy 4. Norbert Victor (D*) since mon/yyyy, 5. Ewa Kawalec (PL) since mon/yyyy 6. Simon Day (UK) since mon/yyyy 7. Stanislav Katina (A) since mon/yyyy
Terms of Reference	(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. (3) To set rules and standards for funding of ISCB members of National Groups and others from countries with exchange control restrictions or barriers. (4) The Subcommittee administers the Conference Awards for Scientists for the annual ISCB meetings.
Report	<p>The Romanian National Group, founded in 2003, and voted for continuation in 2008, still didn't clarify the functioning rules and didn't submit a written statutes by the final deadline, 1 June 2009. The dissolution of the group was proposed to the ExCom. Reason: not respecting the rules of Article 8 from the ISCB Constitution.</p> <p>The Polish National Group organized a short course entitled Generalized Linear (Mixed-effects) Models, supported by ISCB, which took place on 1-3 July, 2009, in Cracow.</p> <p>Discussions about the possible foundation of a new national group in Sri Lanka started with Roshini Sooriyarachchi (who was a CAS award winner in 2008 and she expressed her interest in organizing such a group when we met at the conference in Copenhagen).</p> <p>The last-year change in the terms of reference for the Conference Awards for Scientists (that not only the abstract but the whole poster/presentation had to be submitted), seemed to be a real improvement, since it enabled a better assessment of the submissions. However, this year there were some applications with purely theoretical content, and some others which were mere routine analyses of data sets. We have to make it clearer that such applications are not encouraged by the ISCB.</p> <p>This year there were 9 applications from 9 countries (Cuba, Hungary, India, Iran, Kenya, Pakistan, Poland, Romania and South Africa). The award was granted for 6 abstracts. The authors of the award-winner abstracts are (in alphabetic order):</p> <p>M. Rauf Ahmad (Pakistan), Mausumi Bose (India), Rosa Jimenez (Cuba), Zsolt Lang (Hungary), Samuel M Mwalili (Kenya), Lise Werner (South Africa).</p>
	<ul style="list-style-type: none"> During the AGM, Julia Singer presented the certificates to Rosa Jimenez, Zsolt Lang and Lise Werner. She also asked for volunteers to join the SC.

3.2 Student Conference Awards - KyungMann Kim

Annual Report of Subcommittee	Student Conference Awards						
Report Date	15/Jul/2009						
Report Author(s)	KyungMann Kim						
Subcommittee Start date	mon/yyyy						
Chair	1. KyungMann Kim (USA) since Jan/2007						
Members	1. Carl-Fredrik Burman (S) since Jan/2009 2. Emmanuel Lesaffre (B, Pres. Rep.) since Jun/2009 3. Bianca de Stavola (UK) since mon/2008 4. Vana Sypsa (GR) since mon/yyyy 5. Jean-Christophe Thalabard (F) since Jun/2009 6. Ulrich Mansmann (D) since Jul/2009 Bruno Cesana (I) since mon/yyyy until Jul/2009 Jan Lanke (S) until Dec/2008.						
Terms of Reference	Student conference awards are available for registered postgraduate students to attend the annual conference and present a paper. The Subcommittee shall receive submissions, judge them, and administer the awards. The rules and procedures are announced in a timely issue of the Newsletter and on the ISCB annual conference webpage.						
Report	<p>After many years of service, Jan Lanke (S) resigned from the Subcommittee. Carl-Fredrik Burman (S) joined the Subcommittee following the ISCB Annual Conference in Copenhagen, Denmark in 2008, effectively replacing Jan.</p> <p>Two new members joined the Subcommittee in June 2009: Emmanuel Lesaffre (B) and Jean-Christophe Thalabard (F). The Subcommittee would like to add one additional member, preferably, a female one, for a better gender representation. I would like to take this opportunity to thank Jan Lanke for his service on the Subcommittee and to welcome new members on behalf of the Society.</p> <p>The following members participated in the review and selection process this year: Chair, KyungMann Kim; Members, Carl-Fredrik Burman, Bruno Cesana, Bianca de Stavola and Vana Sypsa; and SPC Chair, Geert Molenberghs. In the past, programme chair of the annual conference has participated in the evaluation and selection process for the award. This will continue in the future as it provides a bridge between the Scientific Programme Committee and the Subcommittee. I would like to thank the Subcommittee members and Geert for their contribution.</p> <p>At the past few annual conferences, the Subcommittee discussed ways to increase the number of applications. I am happy to report that the number has been increasing from 9 in 2006, 11 in 2007, and 12 in 2008 to 15 this year. Whether the discussion had an impact or not, however, cannot be known for certain.</p> <p>This year there were six applications from UK, four from Belgium, two from Italy, and one each from Canada, Germany and Sweden. The Subcommittee selected three applications based on the submitted abstract and summary of the paper. This year's Student Conference Awardees are given below along with their affiliation and the title of presentation:</p> <table border="0"> <tr> <td>Arephin, Muna</td> <td>Queen Mary University of London, UK Order restricted hypothesis testing for three-arm clinical trials</td> </tr> <tr> <td>Bekaert, Maarten</td> <td>University of Ghent, Belgium Estimation of marginal structural survival models in the presence of competing risks</td> </tr> <tr> <td>Van Rompaye, Bart</td> <td>University of Ghent, Belgium Design and testing for clinical trials faced with misclassified causes-of-death</td> </tr> </table> <p>In the past, the Subcommittee and the Awardees got together over dinner during the Annual Conference. From this year, a separate table will be reserved for the Awardees and the Subcommittee members at the Conference Dinner. The fee for the Conference Dinner for the Awardees will be waived.</p> <p>The current evaluation and selection process, all by email, appears to be working well without a hitch, and so the Subcommittee will continue to operate in this way. Specifically once the complete applications are in the hands of the Subcommittee chair, they are sent via email to the Subcommittee members. They are typically given two weeks to evaluate and score the applications using an ordinal scale of 1 (best) to 5 (worst). Once the scores are submitted by all Subcommittee members, the chair goes through the scores and summarized them using a number of different statistics such as mean, median, range, number of 1s and number of 5s. Based on these summary statistics, the chair makes a recommendation to the Subcommittee members. The decision for the final award is made by consensus. Subcommittee members have to excuse themselves if there is a conflict of interest with the applications. The Subcommittee is going to convene on Wednesday, 26 August, 17:30-18:30 to discuss plans for 2010.</p>	Arephin, Muna	Queen Mary University of London, UK Order restricted hypothesis testing for three-arm clinical trials	Bekaert, Maarten	University of Ghent, Belgium Estimation of marginal structural survival models in the presence of competing risks	Van Rompaye, Bart	University of Ghent, Belgium Design and testing for clinical trials faced with misclassified causes-of-death
Arephin, Muna	Queen Mary University of London, UK Order restricted hypothesis testing for three-arm clinical trials						
Bekaert, Maarten	University of Ghent, Belgium Estimation of marginal structural survival models in the presence of competing risks						
Van Rompaye, Bart	University of Ghent, Belgium Design and testing for clinical trials faced with misclassified causes-of-death						

- During the AGM, KyungMann Kim wanted to present the certificates to the winners but unfortunately, none was present.

3.3 Conference Organising - Harbajan Chadha-Boreham

Annual Report of Subcommittee	Conference Organising
Report Date	17/Jul/2009
Report Author(s)	Harbajan Chadha-Boreham
Subcommittee Start date	Jul/2003
Chair	1. Harbajan Chadha-Boreham (CH, Pres. Rep.) since mon/yyyy
Members	2. Lucinda Billingham (UK) since mon/yyyy 3. Bjarne Bodin (DK) since mon/yyyy 4. Lutz Edler (D) since mon/yyyy 5. Emmanuel Lesaffre (B) since mon/yyyy 6. Tim Ramsay (CA) since mon/yyyy 7. Giota Touloumi (GR) since mon/yyyy 8. Zdenek Valenta (CZ) since mon/yyyy 9. David W Warne (CH) since mon/yyyy 10. Koos Zwinderman (NL) since mon/yyyy
Terms of Reference	(1) Bring together ISCB Conference organisers or ISCB members who have an interest in sharing and passing on their knowledge and experience to help future ISCB Conference organisers. (2) Document processes and systems for assisting ISCB Conference organisers. (3) Review and update the documents whenever necessary and promote their usage for improving the procedures or meetings.
Report	<p>The sixth meeting of the subcommittee was held in 2008 during the ISCB Conference in Copenhagen. The future conference organisers (Zdenek Valenta, Nicolas Molinari and Tim Ramsay) were also present at this meeting. The Minutes of the Copenhagen SC meeting were issued.</p> <p>Membership changes: John Whitehead and Catherine Quantin retired in 2008. Tim Ramsay joined the SC during the Copenhagen meeting; Lucinda Billingham and Lutz Edler joined after the 2008 ExCom elections.</p> <p>The revised Conference Organising Guidelines were posted up on the ISCB restricted area last year and the document was circulated to future organisers (Montpellier 2010, Ottawa 2011, Bergen 2012 and Vienna 2013).</p> <p>Following the discussions at last year's conference about taxation in different countries, Koos Zwinderman has provided additional guidelines on "Tax Issues" for the Financial Section of the Conference Organising Guidelines.</p> <p>The ISCB Officers discussed recently whether the presentations given at the ISCB conference should be accessible to the participants. It was agreed to leave this open for the conference organisers to decide if they want to allow access, but the full papers should not be downloaded because of conflict with Statistics in Medicine special issue.</p> <p>Koos Zwinderman has circulated the previous conferences' accounts to future conference organisers, as requested. The accounts have list of sponsors, which are useful for the future organisers.</p> <p>David Warne has assisted with coordinating the SC and some other meetings in Prague. He has also been involved in the ISCB 30 celebrations arrangements.</p>

3.4 Education - Rumana Omar

Annual Report of Subcommittee	Education
Report Date	25/Jul/2009
Report Author(s)	Rumana Omar
Subcommittee Start date	mon/yyyy
Chair	1. Rumana Omar (UK) since mon/yyyy
Members	2. Mike Campbell (UK) since mon/yyyy 3. Nicole Close (USA) since mon/yyyy 4. Erik Cobo (E) since mon/yyyy 5. Catherine Quantin (F) since mon/yyyy 6. Jenö Reiczigel (H) since mon/yyyy 7. Carol Redmond (USA) since mon/yyyy 8. Elisabeth Svensson (S) since mon/yyyy 9. Maria Grazia Valsecchi (I) since mon/yyyy 10. Norbert Victor (D, Pres. Rep.) since mon/yyyy 11. Krisztina Boda (H) since mon/yyyy 12. Jean-Christophe Thalabard (F) since mon/yyyy Havi Murad (ISR) since mon/yyyy until Aug/2009.
Terms of Reference	To support and organise one or two day courses on contemporary methods in clinical biostatistics in locations represented by the Society. Guidelines and a list of courses offered in the past are available.
Report	The ISCB sponsored course on Generalized Linear (Mixed-effects) Models, for target countries, conducted in Poland was successful, report enclosed. A pilot workshop for developed countries is planned for November 2009. Information on this planned workshop is also enclosed.

3.5 Membership - Emmanuel Lesaffre

Annual Report of Subcommittee	Membership
Report Date	24/Jul/2009
Report Author(s)	Emmanuel Lesaffre (with Harbajan and KyungMann)
Subcommittee Start date	Sep/2005
Chair	1. Emmanuel Lesaffre (B) since mon/yyyy
Secretary	2. KyungMann Kim (USA) since mon/yyyy
Members	3. Michal Abrahamowicz (CA) since mon/yyyy 4. Harbajan Chadha-Boreham (CH) since mon/yyyy 5. Philip Hougaard (DK) since mon/yyyy 6. Toshiro Tango (J) since mon/yyyy 7. Norbert Victor (D) since mon/yyyy 8. Bjarne Bodin (DK) since Aug/2007 9. David W Warne (CH) since Aug/2007 10. Maria Grazia Valsecchi (I) since Aug/2007 11. Giota Touloumi (GR) since mon/yyyy 12. Lucy Billingham (UK) since May/2009 John Whitehead (UK) from mon/yyyy until Dec/2006
Terms of Reference	To explore strategies to increase the ISCB membership by means of: 1. Highlighting the unique position of the ISCB, i.e. bringing together clinicians, methodologists, epidemiologists and biostatisticians 2. Make strategic links with medical and epidemiological societies in order to make publicity at their meetings and bring clinicians/epidemiologists with a methodological/biostatistical interest to our ISCB meeting 3. Widen the geographical spread of the ISCB members 4. Ensure the regeneration of our current core membership. 5. Provide guidelines for future conference organisers on choosing a scientific programme committee that will help in widening membership 6. To consider the future of the Newsletter, including ways to support the Editor, procedures for transition of editorship. 7. To maintain the ISCB homepage on the World Wide Web and facilitate placement of annual meeting information on the homepage. 8. To consider other communications with members, such as through email or the World Wide Web.
Report	The Membership Subcommittee meeting was held during the Copenhagen meeting on Monday, 18 August, 2008. The following members were present at the meeting: Michal Abrahamowicz (Canada), Harbajan Chadha-Boreham (Switzerland), Philip Hougaard (Denmark), KyungMann Kim (USA), Emmanuel Lesaffre (Belgium), Toshiro Tango (Japan), Norbert Victor (Germany) and David Warne (Switzerland). Emmanuel had led the efforts during the past few years to link with other statistical societies and to monitor the established links on an ongoing basis, including the need for follow-up on conference dates from competing meetings. Harbajan had volunteered to monitor the links after the end of her term as ISCB secretary. She has been collaborating with Rita Schou this year to update the status of existing links. In addition, she has re-established the links with ISI and assisted with setting up new contacts with GMDS (German Society of Medical Statistics), following a request from Norbert. She has collaborated with the Prague and Montpellier organisers to publicise the ISCB conferences via ISI Events Calendar. At last year's conference the Communications Subcommittee was merged with the Membership Subcommittee with David continuing to be in charge of the ISCB Newsletters. David stated in Copenhagen that the subcommittee needs to provide timely feedback on the ISCB webpage. The proof-reading of the Newsletter has been conducted by the ISCB Officers since the December 2008 issue. In order to publicise the ISCB further to the external statistical communities, Norbert, Emmanuel, Koos Zwinderman, Lutz Edler and Rumana Omar will give presentations at ISI in Durban, South Africa (In a special session dedicated to Biostatistics and ISCB). Emmanuel and Harbajan have submitted their publication, entitled "ISCB: promoting statistical developments in clinical research". Following discussions over the previous years regarding the reduced charge for students' conference dinner, in addition to the conference registration fee and holding the student reception on Sunday evening of the annual conference, these have been put into effect for the Prague Conference. In addition, as agreed in Copenhagen, David and Rita Schou have compiled information about past Student Conference Award recipients and their latest membership status. It was noted that a little over 10% of the participants at the ISCB29 were students. During the Copenhagen Conference, Emmanuel led the new initiative for creating subcommittee on clinical epidemiology as a means to increase participation of clinical epidemiologists in the ISCB annual conferences and reaching out to organizations like the Society for Epidemiology Research. The interested members met in the afternoon of Wednesday, 20 August 2008. After the Copenhagen Conference, Emmanuel passed on this initiative to Norbert, the incoming President. Norbert contacted Vana Sypsa to lead a task force on Epidemiology. This task force consisting of the core members who were present at the Copenhagen meeting have had several exchanges with Vana and the proposals for Terms of References of the new Epidemiology SC will be submitted for approval at the AGM of Prague Conference. At the Copenhagen SC meeting, Emmanuel wanted to explore the idea of the national group for China and to expand membership in Asia in general. KyungMann noted that there were close to 30 delegates at the Copenhagen Conference from Asia including one statistician (industry) from China. He mentioned the recent inaugural symposium of the International Society for Biopharmaceutical Statistics held in Shanghai and the possibility of initiating a contact with the local organizers of the ISBS Symposium in Shanghai or through organization like the International Chinese Statistical Association. However, he cautioned that the economic situation is probably difficult for academic clinical biostatisticians from China to attend overseas conference. It was noted that lessons from eastern European countries and from the Education Subcommittee's activity of offering courses may prove useful in getting this idea off to a start. Another suggestion made at the Copenhagen meeting was to create a National Group pertaining not to one Asian country. Since last year's meeting, Norbert and Rumana Omar (Chair of Education SC) made appropriate propositions to Prof. Xu (Head of the Shanghai Biostatistics group). Prof. Xu responded that he would be happy to circulate information among the members of the Shanghai Biostatistics Forum. The subcommittee will follow this up in collaboration with the President.

3.6 Statistics in Regulatory Affairs - Christoph Gerlinger

Annual Report of Subcommittee	Statistics in Regulatory Affairs
Report Date	16/Jul/2009
Report Author(s)	Christoph Gerlinger
Subcommittee Start date	Sep/1995
Chair	1. Christoph Gerlinger (D), Chair since Aug/2008, member since Mar/2006
Members	2. Harbajan Chadha-Boreham (CH), since Oct/2000 3. Lutz Edler (D) since Aug/2009 4. Tim Friede (UK) since Jan/2009 5. Jen-Pei Liu (TW) since Jan/2009 6. Christos Nakas (GR) since Jan/2009 7. Anna Petroccione (I) since Oct/2000 8. Martin Schumacher (D) since Jan/2005 9. Jørgen Seldrup (F) member since Sep/1995
Terms of Reference	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/her absence, the Vice-President.
Report	The 2008 SIRA Annual Report was written by Jørgen Seldrup and Martin Schumacher presented it at the ExCom meeting. Jørgen Seldrup presented the report at the Annual General Meeting (AGM) in Copenhagen and he officially retired as Chair of SIRA at the AGM. Christoph Gerlinger, who has been a SIRA member since March 2006, followed Jørgen Seldrup as Chair of the subcommittee after the 2008 AGM. A Subcommittee meeting was held during the Annual Meeting in Copenhagen attended by Jørgen Seldrup and Harbajan Chadha-Boreham. On 15 Nov 2008 a call for contributions was sent out to the subcommittee and to all ISCB members on three new CHMP draft guidelines (Guideline on the Investigation of Bioequivalence ¹ , Note for Guidance on Development Safety Update Report ² , and Guideline on Clinical Evaluation of Diagnostic Agents ³) and two FDA guidelines (end of phase II meetings ⁴ and integrated summaries of efficacy ⁵). Several comments from the membership were received on the Diagnostic Agents Guideline. On January 5th, 2009 the sub-committee commented on this guideline. Our comments have also been posted on the ISCB's website ⁶ . The other guidelines were not commented upon. An invitation to comment was issued to the members of the sub-committee and the general ISCB membership on 19 May 2009, concerning the European Draft Guideline on Missing Data in Confirmatory Clinical Trials ⁷ . The EMEA's deadline for comments is by end of October. However, SIRA would like to receive all comments by the end of July to allow the SIRA for consolidation and editing the ISCB's comments. We are also aware that the FDA in the context of the Critical Path Initiative intends to publish guidance on non-inferiority, adaptive designs and missing data in the near future.

¹ <http://www.emea.europa.eu/pdfs/human/qwp/140198enrev1.pdf>

² <http://www.emea.europa.eu/pdfs/human/ich/30934808en.pdf>

³ <http://www.emea.europa.eu/pdfs/human/ewp/111998enrev1.pdf>

⁴ <http://www.fda.gov/cder/guidance/8297dft.pdf>

⁵ <http://www.fda.gov/cder/guidance/7694dft.pdf>

⁶ http://www.iscb.info/iscbdocs/ISCB_Comments_EMEA_Diagnostic_agents_guideline.doc

⁷ <http://www.emea.europa.eu/pdfs/human/ewp/177699endraft.pdf>

3.7 Vaccines – Jos Nauta

Annual Report of Subcommittee	Vaccines
Report Date	10/Jul/2009
Report Author(s)	Andrew Dunning
Subcommittee Start date	Mar/2008 (first meeting was Dec/2007)
Chair	1. Andrew Dunning (USA) since Dec/2007
Secretary	2. Jos Nauta (NL) since Dec/2007
Members	3. Ivan Chan (USA) since Dec/2007 4. Marc Fourneau (Belgium) since Dec/2007 5. Allen Izu (USA) since Dec/2007 6. Jingyee Kou (USA) since Dec/2007 7. Larry Moulton (USA) since Dec/2007 8. Julia Singer (Austria) since Dec/2007 9. Jukka Jokinen (Finland) since Apr/2009 10. Koos Zwinderman (NL; Pres. rep.) since May/2009 Catherine Quantin (France; Pres. Rep. from mon/yyyy until May/2009) Paddy Farrington (UK)+ since Dec/2007 until Mar/2009
Terms of Reference	(1) Create a professional platform for statisticians active in the research on vaccines (3) Discuss new regulatory guidelines and comment upon draft guidelines, in collaboration with the subcommittee on Statistics in Regulatory Affairs (2) Keep up-to-date, discuss, apply and encourage relevant statistical and methodological developments (4) Encourage professional development (5) Organise symposia in the annual ISCB meetings or in collaboration with ISCB on methodological developments in vaccines research
Report	The Vaccines Sub-Committee has established and extended its activities in the past year. The sub-committee is organizing a mini-symposium at the 2009 conference in Prague; topics on the program include interim analyses and multiplicity in vaccine clinical trials. The sub-committee tracks vaccine sessions at statistical conferences and encourages committee members and others to organize such sessions. The sub-committee tracks statistical sessions at vaccines conferences and encourages committee members and others to organize such sessions. A mailing list of statisticians working in vaccines research is maintained, there are presently more than 250 statisticians on the list. A newsletter is sent quarterly; newsletters #4 through #7 have been sent in the past year. In addition to information on the mini-symposium and upcoming conference sessions, the newsletter includes synopses of recent publications in the field of the statistics of vaccines research. A website for vaccine statisticians has been established this year at www.iscb-vaccines.info showing the sub-committee's mission (terms of reference), history, current members, upcoming symposia and conference sessions, recent publications and previous symposia, and a 'contact us' page. The sub-committee is making progress towards assembling lists of selected readings in topics in areas of the statistics of vaccines research. The lists are intended to encompass background reading for new statisticians working in vaccines; external reviewers are reviewing the selections. A vaccines mini-symposium/workshop is being planned for the 2010 conference in Montpellier; it is hoped to have the program finalized by the time of the 2009 conference. Andrew Dunning will be rotating out of the chair of the sub-committee at the 2009 annual conference. Jos Nauta will be the new chair.

- The motion for the continuation of the above 7 SCs was proposed by Norbert Victor, seconded by Stephen Senn and approved unanimously.

3.8 Epidemiology TF => SC - Vana Sypsa

Annual Report of Task Force/ Subcommittee	Epidemiology
Report Date	27/Jul/2009
Report Author(s)	Vana Sypsa
Subcommittee Start date	Aug/2009
Chair	1. Vana Sypsa (Greece) since Aug/2009
Members	2. Adriano Decarli (Italy) since Aug/2009 3. Elaine Pascoe (Australia) since Aug/2009 4. Ewout Steyerberg (Netherlands) since Aug/2009 5. Geir Egil Eide (Norway) since Aug/2009 6. Harbajan Chadha-Boreham (Switzerland) since Aug/2009 7. Helge Gydesen (Denmark) since Aug/2009 8. Marie Reilly (Sweden) since Aug/2009 9. Michal Abrahamowicz (Canada) since Aug/2009 10. Stephen Walter (Canada) since Aug/2009 11. Tim Ramsay (Canada) since Aug/2009 12. Willi Sauerbrei (Germany) since Aug/2009
Terms of Reference	Advise the Scientific Programme Committee of the annual ISCB meetings, if needed, on relevant topics in epidemiology for establishing invited sessions and choosing invited speakers. Establish connections with Epidemiological Societies and organise mutual sessions, courses or workshops at our conferences or elsewhere. Generate awareness and discussions in the Society of guidelines for conducting, analysing and reporting epidemiological studies.
Report	The terms of reference of the subcommittee have been prepared and submitted to the ExCom for approval in Prague.

- Harbajan Chadha-Boreham announced that the setting up of the SC i.e. transformation of the active taskforce into a SC, had been approved by the ExCom and Vana Sypsa would be its Chair.

4. FUTURE MEETINGS

4.1. 2010 Montpellier [31] – Gilles Ducharme

- A short presentation of the scientific and cultural highlights of next year's conference was presented (29 August – 02 September). There were no comments. [A 2-page brochure was available in the conference bag.]

4.2. 2011 Ottawa [32] - Tim Ramsay

- The initial plans for the 2011 meeting were presented; more details will be worked out in the coming months and presented next year.
- Comments: Marc Buyse if such a non-joint meeting might draw a lower attendance, especially from Europe, and encouraged the organisers to advertise it widely. Tim agreed this was possible but more US and Canadian attendees would be attracted, and the cost of living and flying to North America is not so high. A clash of dates with the Joint Statistical Meetings has been avoided but the chosen week (21-25 August) does overlap with ISI in Dublin, so it will be investigated whether the week before could be a better choice. Emmanuel Lesaffre added that the Membership SC has built a list of links to many other societies and there's an idea to have national ISCB representatives in each country to distribute news and posters. Norbert Victor said that to justify the "I" in ISCB, we need to be international and not only European. Michal Abrahamowicz noted that the overlap between ISCB and ISI is very small and Canada is indeed inexpensive. Tim concluded by welcoming help with advertising the conference.

4.3. 2012 Bergen [33], 2013 Vienna [34], 2014+ meetings – Harbajan Chadha-Boreham

- Harbajan Chadha-Boreham summarised progress for the next few meetings. Proposals have been received for 2012 (Geir Egil Eide) and 2013 (Michael Schemper) and ideas are forming for meetings for 2014 and later. A suggestion to have a 4th joint meeting with SCT in Europe is also being discussed.
- Comments: Maria Grazia Valsecchi pointed out that a joint meeting may be a lot bigger and so would lose some of the atmosphere of a normal ISCB meeting; she asked why not hold it in US as the last was in Europe. Mar Buyse thought it would be too soon after Ottawa to have another north American meeting. Stephen Senn wondered about a compromise location, e.g. Reykjavik... Marc Buyse reminded us that the first joint meeting in Europe, Brussels in 1991 had been a success. Norbert Victor concluded by saying nothing was fixed yet.

5. HONORARY MEMBERSHIPS - NORBERT VICTOR

- Norbert Victor read out 2 “laudations” for John Whitehead and Stephen Senn.

Honorary Memberships

Starting last year, 2008, the Officers have been discussing the possibility of awarding some members with an Honorary Membership on the occasion of the 30th anniversary of our Society. After taking a closer look on the all services done for ISCB, we proposed to give the Honorary Memberships to Stephen Senn and John Whitehead. The ExCom unanimously supported this proposal which has now to be submitted to the AGM.

Stephen and John both meet the conditions of Article 4.01 of our Constitution in an excellent way: they are distinguished biostatisticians and have given service of exceptional value and duration to ISCB.

Stephen Senn is one of the most faithful ISCB members: He attends here his 25th annual meeting, has given many very exiting lectures (among them the keynote lecture in 2003), he contributed 10 papers to the congress issues of Statistics in Medicine, and he has taught several pre-conference courses, as well as courses in target countries. Stephen became an ordinary ExCom member in 1991 and served as Secretary from 1992 to 1995. He also served the Society in many other functions: He was member of several Scientific Programme Committees (SPCs, once, Dijon 2003, acting as Chair), editor of the Dijon congress issue of Statistics in Medicine, LOC member for ISCB15 in Basle, and Secretary of the SC “Statistics in Regulatory Affairs”. As Stephen is accepted worldwide – both in academia and the pharmaceutical industry – as an outstanding biostatistician, there is no need to enumerate his scientific merits here.

John Whitehead’s list of merits and services to ISCB is as long as that of Stephen; he is without any doubt one of the most loyal members since the society was established: John attended the first ISCB meeting 1979 in Brussels and most of our meetings after that, he presented a large number of papers, he taught several ISCB courses and he contributed the highest number (12) of articles to our congress issues of Statistics in Medicine. Apart from our first two Honorary Members, John has been the ExCom Member with the longest period of service; this period of twelve years includes four years as Treasurer, two years as President and three years as Vice-/Past-President. John also served the Society in many other functions, e.g. as member of several subcommittees, chair of the Student Conference Awards committee, member of SPCs and member of the LOC in 2003. John’s reputation as outstanding scientist is undisputed. Therefore, I would like to mention only two of his prominent merits: his role as driving force and teacher in the Biostatistics Master programme in Reading, and his widely used monograph on sequential trials.

- A majority approval was required from the AGM attendees and the proposal by Norbert Victor was accepted unanimously.

6. ANY OTHER BUSINESS – DAVID W. WARNE

- Zdenek Valenta, LOC Chair, made a short announcement about the Conference Dinner.
- Marc Buyse asked if a time other than the AGM could be found to present the awards, e.g. the Dinner. Norbert Victor said that this will be considered by the Officers.

Advert: MPS, Lancaster (UK)



Medical and Pharmaceutical
Statistics Research Unit



The MPS Research Unit is pleased to announce our programme of short courses for 2010 on advanced concepts in the design and analysis of clinical trials. Our courses are aimed at statisticians working in clinical research. Courses take place in the new purpose-built and attractive accommodation of the Postgraduate Statistics Centre. Presenters will be John Whitehead, Anne Whitehead, Thomas Jaki, Helene Thygesen and Ting-Li Su.

CALENDAR FOR 2010

25-28 January	Pharmacological Modelling
8-11 February	Survival and Event History Analysis
12 February*	Genomics: Technologies and Data Analyses
22-25 February	Adaptive and Bayesian Methods in Clinical Research
19 May	Design of Early Phase Clinical Trials

*Course material for the Genomics workshop will be available for self-study via the web from 15 January, which is the registration deadline. A one day workshop to complete the course will be held at Lancaster on 12 February.

FURTHER DETAILS AND BOOKING: For details of these and other courses offered by the Postgraduate Statistics Centre, go to <http://www.maths.lancs.ac.uk/psc> or contact Angela Mercer, Postgraduate Statistics Centre, Department of Mathematics and Statistics, Fylde College, Lancaster University, Lancaster LA1 4YF, UK.
Tel: +44 1524 593064 Fax: +44 1524 592681 email: a.j.mercer@lancaster.ac.uk

Elections for the Executive Committee 2011-12: Early Warning!

From Emmanuel Lesaffre, Chair of the Nominations Committee

In accordance with the Constitution, we ask for nominations for positions on the Executive Committee for 2011-12. At the end of 2010, the situation will be:

Norbert Victor	Will retire as President and becomes Past President for one year, 2011.
Harbajan Chadha-Boreham	After being Vice President for 2009-10, will become President for 2011-12 and Past-President for 2013.
Koos Zwinderman	Will end his 2 nd term as Treasurer and is not eligible for re-election as Treasurer or Secretary but could be elected as Vice President.
David W Warne	Ends his 1 st term as Secretary and is eligible for re-election as Treasurer, Secretary or Vice President.
Adriano Decarli, KyungMann Kim	End their 2 nd terms as Ordinary members and are not eligible for re-election as Ordinary members, but are eligible for re-election as Treasurer, Secretary or Vice President.
Lucinda Billingham, Krisztina Boda, Lutz Edler, Ulrich Mansmann, Jean-Christophe Thalabard, Giota Touloumi	End their 1 st terms as Ordinary members and are eligible for re-election as Ordinary members, or as Treasurer, Secretary or Vice President.
David W Warne	Wishes to continue as News Editor.
Bjarne Bodin	Wishes to retire as Webmaster.

For the end of term it is meant the end of the calendar year (2010).

Nominations for

- Vice President,
- Secretary,
- Treasurer and
- 8 ordinary members

are therefore sought.

To make a nomination, please download the form from the web

[http://www.iscb.info/iscbdocs/Template_Nomination_2010.doc] and send it to the

Chair of the ISCB Nominations Committee, Emmanuel Lesaffre,

(e.lesaffre@erasmusmc.nl). Each nomination will require the signatures of the Proposer, a Secunder and of the Nominee confirming a willingness to serve. Completed and signed nomination forms must be received no later than 31 August 2010. (Faxed or scanned forms are acceptable.)

If there are more nominees than vacant positions, an electronic ballot will be held.

Please note the following clauses from the Constitution:

“(6.02) The Committee shall consist of the four Officers and at least five but not more than eight other members (“Ordinary members”), plus the Past President, who shall serve only for the calendar year immediately following the Presidency, and co-opted members.”

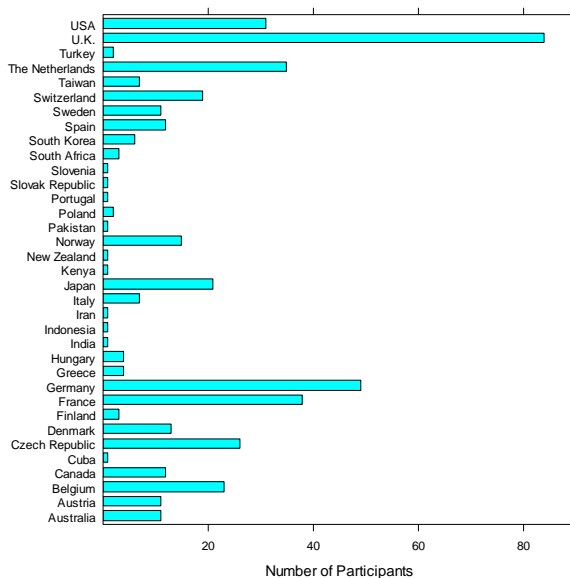
“(6.03) The Ordinary members, who shall be Members for at least the calendar year prior to nomination, must be elected by ballot; their full term of office shall be two calendar years and they shall be eligible for re-election for one further full term up to a maximum of four consecutive calendar years.”

From Zdenek Valenta, on behalf of the LOC of the ISCB30

The 30th Annual Conference of the ISCB is now part of the Society's history. However, for me and some of my colleagues, its preparation was part of our everyday lives for almost four years. If I may, let me ask you for your kind attention one last time to briefly bring back some memories, recall a few events and examine some numbers which altogether illustrate the atmosphere we seemed to have enjoyed when the event finally took place in the city of Prague, Czech Republic.

The Conference venue was the University of Economics in Prague, which has recently seen some additions to its older buildings. The Conference dates were 23-27 August 2009. We enjoyed two larger lecture rooms ('aulas') and quite a number of smaller ones, which altogether suited very well the total number of 460 participants. Their profile by the country of residence is shown in Figure 1. Although historically this was by no means a record number, given the expected impact of global crisis, we were more than satisfied to see such a great crowd attending the Congress.

Figure 1: Number of Participants by the Country of Residence



As usual, the annual event has begun with the launch of pre-conference courses. This year we had four on the menu and their mix was setup by the chair of the Scientific Programme Committee, Geert Molenberghs. James Carpenter gave his course on the *Analysis of Incomplete Data*. For several years now this course has been very popular amongst medical statisticians, so we were little surprised to see that 37 Conference participants signed up for it. Stephen Senn gave another course entitled *Clinical Trial Methodology*, with 33 participants in attendance. Garret Fitzmaurice flew over the Atlantic to equip 23 of his listeners with the background of *Longitudinal Data Analysis*. Finally, another transatlantic flight brought another fine lecturer, Dhammika Amaratunga, who gave a course on *Bioinformatics*, which briefly examined the microarray data technology, and was attended by 15 Conference participants. Overall, the pre-conference courses appeared to be a great success, we have had a very positive feedback on the content and the way the courses were handled. Sunday courses were a great warm up before the official launch of the Conference on Monday.

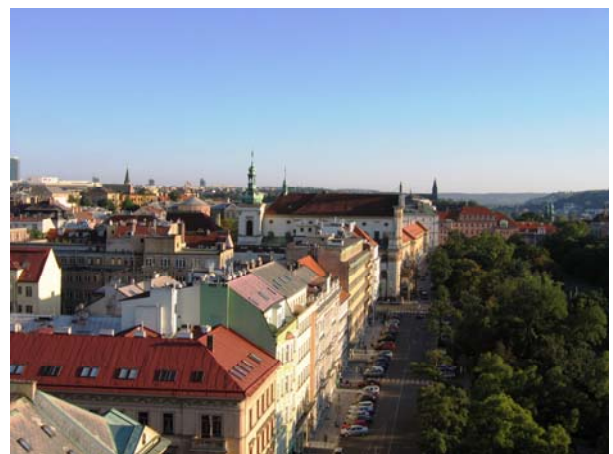
Over the first three days, the Conference participants could choose from among 169 scientific presentations, 15 of which were invited. Themes of the invited sessions included '*Indirect Comparisons of Health Care Interventions*', '*Joint Modelling of Longitudinal and Survival Data*', '*Regulatory Affairs*', '*Incomplete Data*' and '*Statistical Methods in HIV/AIDS Research*'. On Wednesday, Marc Buyse gave the ISCB President's invited lecture entitled "*On trial endpoints that combine clinical relevance and statistical efficiency: 'Analyze the data, the whole data, and nothing but the data'*". Twenty-five sessions were devoted to contributed themes. Two mini-symposia were part of the Thursday Conference menu. One mini-symposium was dedicated to Biomedical Informatics and the other to Statistics in Vaccines Research.

Highlights of the social programme were the New Town Hall (founded in 1377) Reception on Monday evening and the Conference Dinner on Wednesday night.

Here are just a few snapshots from the New Town Hall just before opening the Welcome Party of the ISCB30.



A nice view from the top of the New Town Hall on the surrounding city.



The Dinner was served in Kaiserštejn Palace (founded in 15th century) in Prague's Lesser Town. Both events were well attended and the response gathered from the participants was overwhelmingly positive. On Wednesday night the president of the Society Norbert Victor bestowed honorary ISCB memberships on two distinguished scholars, John Whitehead and Stephen Senn, both of whom have significantly contributed to the scientific growth and professional development of the Society over the last three decades of its existence.



Books for Review by Sylvain Larroque

Books for review:

Author(s)	Title	Publisher (year) ISBN	Reviewer
1. Chow, Shein-Chung	Design and Analysis of Bioavailability and Bioequivalence Studies, Third Edition	CRC (2009) 978-1-58488-668-6	
2. Cosmatos, Dennis	Translational Medicine	CRC (2009) 978-1-58488-872-7	
3. Herson, Jay	Data and Safety Monitoring Committees in Clinical Trials	CRC (2009) 978-1-4200-7037-8	
4. Peace, Karl E.	Design and Analysis of Clinical Trials with Time-to-Event Endpoints	CRC (2009) 978-1-4200-6639-5	
5. Krzanowski, Wojtek J.	ROC Curves for Continuous Data	CRC (2009) 978-1-4398-0021-8	
6. Gohlmann, Heinrich	Gene Expression Studies Using Affymetrix Microarrays	CRC (2009) 978-1-4200-6515-2	
7. Julious, Steven A.	Sample Sizes for Clinical Trials	CRC (2009) 978-1584887393	

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. Regretfully, 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.).

Sylvain Larroque:

sylvain.larroque@merckserono.net

Book publishers' webpages:

Hodder Arnold	www.hoddereducation.co.uk/RVE99a510f93213434c8b6939f2cb4789e5,..aspx
Blackwell	www.blackwellpublishing.com/subjects/PB/
Cambridge University Press	www.cambridge.org/uk/browse/default.asp?subjectid=1007745
CRC (Taylor and Francis)	www.crcpress.com/shopping_cart/categories/categories_products.asp?parent_id=104
Oxford University Press	www.oup.co.uk/academic/science/math/
Springer	www.springer.com/east/home/statistics?SGWID=5-10128-0-0-0
Wiley	www.wiley.com/WileyCDA/Section/id-300665.html

Books for Review (continued)

Books reviews in this issue:			
Author(s)	Title	Publisher (year) ISBN	Reviewer
1. Thomas D. Cook and David L. DeMets	Introduction to Statistical Methods for Clinical Trials	CRC (2008) 9781584880271	Rainer Muche (Germany)
2. Shein-Chung Chow, Mark Chang	Adaptive Design Methods in Clinical Trials	CRC (2006) 978-1584887768	Francois Aubin (France)
3. Michael J. Daniels, Joseph W. Hogen	Missing data in longitudinal studies (Strategies for Bayesian modeling and sensitivity analysis)	CRC (2008) 9781584886099	Maarten Schipper (Netherlands)
4. H. Brown and R. Prescott	Applied Mixed Models in Medicine (Second Edition)	Wiley (2006) 0-470-02356-2	Marie Reilly (Sweden)

Books sent out recently:			
Author(s)	Title	Publisher (year) ISBN	Reviewer
1. D. C. Hoaglin, F. Mosteller and J. W. Tukey	Exploring Data Tables, Trends, and Shapes	Wiley (2006) 0-470-04005-x	Gaj Vidmar (Slovenia)
2. David A. Freedman	Statistical Models, Theory and Practice	Cambridge (2005) 780521671057	Pablo Emilio Verde (Germany)
3. Wojtek Krzanowski	Scientific Principles and Techniques in Scientific and Social Research	Oxford (2007) 978-0199213108	Maciej Gorkiewicz (Poland)
4. Dankmar Böhning, Ronny Kuhnert and Sasivinal Rattamisiri	Meta-analysis of binary data using profile likelihood	CRC (2008) 978-1584886303	Guido Knapp (Germany)
5. Geoff Der, Brian S Everitt	A Handbook of Statistical Analyses Using SAS (3 rd ed)	CRC (2008) 978-1584887843	Salah Ghabri (France)
6. Oleg Demin, Igor Gorayanin	Kinetic Modelling in Systems Biology	CRC (2009) 978-1584886679	Tiberiu Postelnicu (Romania)
7. Ronglin Wu, Min Lin	Statistical and computational pharmacogenomics	CRC (2008) 978-1584888284	Victor Moreno (Spain)
8. Bengt D Furberg, Curt D Furberg	Evaluating Clinical Research: All that Glitters is not Gold (2 nd ed.)	Springer (2007) 978-0387728988	Gerd Rosenkranz (Switzerland)
9. A. C. Atkinson, A. N. Donev and R. D. Tobias	Optimum Experimental Designs, with SAS	Oxford (2007) 978-0-19-929660-6	Nazneen Shariff (India)

Books sent for review quite a long time ago			
Author(s)	Title	Publisher (year)	Reviewer
1. Frank R. Hampel, Elvezio M. Ronchetti, Peter J. Rousseeuw and Werner A. Stahel	Robust Statistics: The Approach Based on Influence Functions	Wiley (2005) 0-471-73577-9	Lars Krogsgaard Thomsen (Denmark)
2. J. Edward Jackson	A User's Guide to Principle Components	Wiley (2003) 0-471-47134-8	Nicole Close (USA)
3. J M Bernardo et al (eds.)	Bayesian Statistics 7	Oxford University Press (2003) 0-19-852615-6	Stefan Tigan (Romania)
4. John Verzani	Using R for Introductory Statistics	Chapman & Hall/CRC (2005) 1-58488-450-9	Justin Clayton (USA)
5. J. Rick Turner	New Drug Development: Design, Methodology, and Analysis	Wiley (2007) 978-0-470-07373-5	Tim Friede (UK)
6. Eric Stallard, Kenneth G. Manton and Joel E. Cohen	Forecasting Product Liability Claims	Springer (2002) 0387949879	Simon Day (UK)
7. Richard J. Hayes, Lawrence H. Moulton	Cluster Randomised Trials	CRC (2009) 978-1584888161	Chris Metcalfe (UK)

The book edited by Cook and DeMets describes the main aspects of statistical methods in the planning and realisation of clinical trials. The book is a common opus of 12 authors of the Department of Biostatistics and Medical Informatics of the University of Wisconsin who wrote the 12 chapters in different formations. The book is orientated at the considerations that have usually to be realized before designing a study protocol of a clinical trial, typically a RCT. The planning phase is therefore in the foreground rather than the analysis phase. This is reflected in the themes covered in the book.

First of all, Chapter 1 gives an overview of the aim of a controlled clinical trial and mentions some important basic conditions like guidelines and standards or control bodies. In the following chapters, statistical aspects for the preparation of the protocol are specifically described, like study design, planning of study size, randomization, and interim analyses. Chapter 2 describes the definition of the problem and the importance of the specification of the outcome. In Chapter 3 the different study designs are introduced, from "simple" parallel group designs to non-inferiority and adaptive designs. Important items for the planning of studies are the planning of the study size and the randomization, both are presented in Chapters 4 and 5. Chapter 6 describes the aspects of data quality. Chapters 7 and 8 are illustrating special analysis situations for survival and longitudinal studies. Especially in the oncological field, but not only there, many aspects of patients' life quality have to be considered today. The definition, choice of instruments and aspects of analyzing quality of life (QoL) are presented in Chapter 9. The following Chapter 10 depicts the accompanying monitoring of studies, i.e. in the context of interim analyses in group sequential study designs. Before in the closing Chapter 12 the conclusions and the report of clinical studies are in the foreground, Chapter 11 goes into different further aspects in connection to clinical trials like selection effects, missing data, evaluation of subgroups, and multiple testing.

Altogether, all important aspects of planning and execution of clinical trials have been mentioned and described. The authors are assuming clinical trials which test hypotheses concerning the therapies in use. Accordingly, they have a frequentist view on planning, realization, and analysis of studies and stuck to it throughout all chapters. Therefore, the confirmatory aspects of the trials are put in the foreground, the problem of explorative analyses in clinical studies is described in Chapter 11 (miscellaneous) under the keywords analyses of subgroups and multiple testing. Complex regression approaches are introduced in the chapters about survival analyses and longitudinal studies.

In the preface, the authors mention that the book is meant as an introduction to statistical methods for clinical trials for graduate students of statistics or biostatistics. Therefore, at the end of most of the chapters some exercises can be found which should improve the comprehension of the text. Unfortunately, there are no solutions available, neither in the book, nor in the Internet. For some formula passages, a basic education in mathematics is useful. But mainly, the methods are described verbally. The book can even be used as reference book for scientists after their academic studies. The necessary formulas and figures are given and illustrated. The book is very voluminous, however, some practical examples could have been included for more evidence with respect to different aspects.

All in all, the book is written very user-related and refers mainly to students and scientists who are planning, reviewing or executing clinical trials. The perspective from the frequentist viewpoint with attention on RCT's is related to the practice of trials and is well comprehensible. Especially the last-mentioned aspects in combination with the practical use make this book worth reading. I can recommend the book as background reading for teaching in mathematical biometrics and for the advice of scientists who are planning clinical trials.

Polish National Group Report

From Ewa Kawalec

The Polish National Group of ISCB consists now of 67 members. We meet usually twice a year (in June and December) at scientific meetings. At the meeting in December 2008 our members gave six lectures on different topics followed by a discussion.

Instead of a summer scientific meeting, our group, with a financial support from ISCB, organised a three-day course on "Generalized Linear (Mixed effects) Models", which took place on 1-3 July, 2009, in Cracow (Poland). The course covered the fundamentals of the Generalized Linear Models (GLMs) and of the Generalized Linear Mixed Models (GLMMs). Real life datasets were used to illustrate applications of the presented methodology. Practical

implementation of the models were illustrated during computer sessions by using R. The course was taught by Tomasz Burzykowski from the Hasselt University in Belgium and Andrzej Galecki from the University of Michigan in Ann Arbor (USA) and was very well received. 29 persons (out of 34 registered) participated in the course.

The next scientific meeting is scheduled for December 2009. The homepage of our group (www.iscb.pl in Polish) introduces our Group to Polish statisticians and others who are interested in application statistics to medical research.

Czech Republic National Group Report

From Zdenek Valenta

On 11 September 2009, the Czech National Group (NG) of the ISCB celebrated 3 years of its official existence. The NG consists of 30 full members. The Group's leadership had a three year mandate which expired in September 2009. Consequently, new elections had to take place. In accordance with the Group's Constitution, the elections were carried out counting the votes registered at the Assembly of Members, which took place on 1 October 2009, and those registered later via e-mail ballot. As a result, on 23 October 2009, the existing leadership was confirmed for the next three years by the election committee headed by Marek Brabec. The Group's leadership continues to serve as follows: Zdeněk Valenta (chairman), Marek Malý (vice-chairman), Věra Lánská (treasurer). Jindra Reissigová was confirmed to serve as an internal auditor for the next three years as well.

The Group helped organise the 30th Annual Conference of the ISCB, which took place 23-27 August 2009 in Prague, Czech Republic. Many Group members were involved as members of the Local Organising Committee: Marek Malý, Věra Lánská, Jindra Reissigová, Arnošt Komárek, Marek Brabec, Jana Zvárová and Zdeněk Valenta. Others served on the Scientific Programme Committee: Michal Kulich, Jana Zvárová and Zdeněk Valenta. In organising the 30th anniversary event the Group received much support from the conference organising company Guarant International Ltd. Of all the great people at Guarant, I should like to mention Jitka Puldová, who exercised great leadership over her team and kept a great team spirit in cooperation with the Organisers. The Group members are currently busy with

preparing the financial audit of the Conference accounts for the ISCB and the municipal finance bureau.

Obviously, most of this year's activities of the Czech National Group were linked to supporting the organisation of the annual event. However, the Group's professional endeavours did not seem to have been adversely affected because of its involvement in the Conference-related organisational activities. In 2009 the Czech NG organised three scientific seminars. On 22 January 2009, the Group welcomed Andrea Kvitkovičová from the Dept. of Probability and Mathematical Statistics at the Faculty of Mathematics and Physics, Charles University in Prague. Her presentation was entitled "Modelling of infectious diseases: monotonicity problem and fractional polynomials in modelling sero-prevalence data". The second seminar took place on 29 April 2009, when the Group welcomed a scientific team from the Institute of Mathematics and Statistics at Masaryk University in Brno, headed by Ivana Horová. She and her colleagues, Zdeněk Pospíšil and Jiří Zelinka, gave a lecture entitled "Estimating the risk function based on cancer cells proliferation modelling". A third seminar took place immediately after the Assembly of the NG Members on 1 October 2009. The audience listened to the presentation entitled "Genome-wide Analysis of Genetic Predisposition of Primary Acute Myocardial Infarction in the Czech Population", given by the Group's chairman, Zdeněk Valenta from the Institute of Computer Science at the Academy of Sciences of the Czech Republic. Recorded contributions were made available to all the Group's members via secured web interface.

Hungarian National Group Report

From Jenő Reiczigel, Krisztina Boda and Peter Vargha

The Hungarian National group has 44 members. In 2009 we continued our regular group meetings with presentations given by the members. Attendance varied between 10 and 20. In the first half of the year, we continued our book-reading seminar based on "Categorical Data Analysis" by Alan Agresti. As our last meeting before the summer vacation, we organised a half-day excursion to the hills in Buda in June.

Some of us attended the ISCB 2009 conference in Prague and reported on the most interesting lectures and posters at the September meeting of the National Group.

Our general meeting took place on 13 November in Budapest. Here a summary report of 2009 was given by the representatives, then we discussed our plans for 2010. We decided to go on with our book-reading

seminar, and to publish a newsletter with two issues a year. To make the career in biostatistics more popular and appealing for the young, we decided to look for sponsors and give the prize "Young biostatistician of the year" in each year from 2010. Winners would also become members of ISCB for one year.

The National Group was invited to be co-organiser of the 9th Hungarian Conference on Biometrics and Biomathematics held in Budapest in 2011. We decided to accept the invitation which will imply much organisational work for us in 2010.

This book focuses on the use of mixed models in the analysis of data from clinical trials. Starting from simple artificial examples, the authors lead the reader through the challenges of modelling data from multi-centre trials and experiments with repeated measures. Chapter 1 provides an intuitive introduction to the need for mixed models in this range of applications, and to the concepts of “balance” and “containment”. A review of Normal mixed models is provided in Chapter 2, where model fitting is presented from the likelihood and Bayesian perspectives, and practical examples are worked out complete with model checking, consideration of the role of missing data, and SAS code. In Chapter 3, Generalised Linear Mixed Models are introduced and fitted using likelihood functions, with a practical application introducing the concept of “random effects shrinkage” and a discussion of the interpretation of the dispersion parameter in GLM and GLMM. Chapter 4 deals with mixed models for ordered categorical data using ordinal logistic regression, and extends to the use of generalized logit links for unordered categorical data where the proportional odds assumption is no longer appropriate. Multi-centre trials and meta-analysis are presented in Chapter 5, repeated measures data in Chapter 6, and cross-over trials in Chapter 7. Chapter 8 provides a wide range of “other applications of mixed models” that presents the potential of mixed models not only in randomised trials but in numerous other designs. Finally, Chapter 9 provides a good summary of statistical packages for fitting mixed models, though sadly it does not mention R, which is widely used by the statistical community.

There are several features of this book that enhance its usefulness in applied work. Chapter 8 is very informative, showing as it does how mixed models lurk in many familiar data structures: nested case-control studies, inter- and intra-rater agreement, cluster sample surveys and more. The book might be made more appealing to non-clinical-trialists if this material was introduced earlier, and the reader then encouraged to see the generality of the methods in Chapters 2-7, which are currently almost exclusively focused on clinical trials. Another welcome feature of the book is the presentation of a close-up view of the elements of the matrices (e.g. Table 6.1) involved in the mixed models. This is most helpful for readers who wish to grasp the assumptions of their models but who are not mathematically inclined or familiar with the usual matrix equations. The didactic style of the book is also apparent from the way in which the authors return to various practical issues and discuss them in relation to data examples, for example in Section 2.5.3. The provision of the detailed commands and output from SAS PROC MIXED would be welcome to SAS-using readers who recognise their own data problem in some of the contexts provided, and wish to try implementing some models. However, it is to be hoped that this will not encourage a “black-box”

approach to running these complex models that need a certain level of statistical experience to handle appropriately.

For a book aimed at “applied” readers, there are some theoretical details that could probably be omitted, or at least skipped or placed elsewhere (e.g. in an Appendix). Examples are Sec 3.1.6 which discusses the exponential family and the subsequent Sec 3.2 where the reader is advised to skip some few details although it appears that they could skip much more without losing the applied message. It is also questionable whether an applied audience should be presented with models that the authors tell us include carry-over effects for completeness rather than for good practice, as such an audience would likely benefit more from critical appraisal of what is best practice: this issue is further complicated by some rather unclear explanations of carry-over effects. Other shortcomings are the lack of reference to other work where the authors themselves claim “no experience” (p133) and lack of information on which software packages are involved where the reader is told that the method is “not possible in some software packages” (p133). The discussion of case-control studies (p339), which would be most welcome to epidemiologists not involved in clinical trials, is compromised by unclear and confusing explanations: the reader is told that each matched set “may” contain cases and controls, although clearly a set with non controls is no longer a matched set and cannot contribute to a matched analysis. On this same page, lines 7-9 from the bottom are not coherent, as if the variables are indeed “matching” variables, then one would assume they cannot be associated with the group.

In addition to a number of minor typographical and grammatical errors, there are some important errors that could create difficulties for the reader and that will no doubt be corrected in subsequent editions. These include: the equation for θ in the centre of page 56 should have y_5 and y_3 in place of μ_5 and μ_3 ; the plots on page 91 and the corresponding text on page 90 cannot be interpreted without the observation index appearing as a label on the plot; on page 132, the word “predicted” in line 11 from the bottom should read “observed”; the matrix P on page 160 should have P_{45} and not P_{12} in the bottom right off-diagonal positions (i.e. visits 1 and 2 for patient 2); the language on page 396 is confusing, as “treatment groups” and “breast screening” would seem to refer to the same strata.

In summary, the book has several features that should make it useful for applied scientists, but the title suggests more general material than what is presented: the emphasis on clinical trials, and the large number of pages dedicated to SAS (which is the only software output) might have been reflected somehow on the cover.

This is a very elaborate monograph on the current state of affairs around the topic of missing data in longitudinal settings. The book roughly consists of three parts. An introduction of necessary materials, which include the longitudinal data setting and notations, Bayesian analysis, covering MCMC as well, and missing data terminology make up the first part. The second part covers the analysis of longitudinal data with missing observations both under the assumptions of the missing data being missing completely at random (MCAR) or missing at random (MAR). It is shown that under MAR, the outcome of the analysis strongly depends on the specification of the dependence structure of the data.

The last and most substantial part of the book handles the situation when neither MCAR nor MAR holds. In this setting the missing data mechanism is called missing not at random (MNAR) and cannot be ignored. Therefore it has to be specified explicitly, when performing an analysis. This is the most novel part of the book and directions of present-day research on this topic are given.

The authors give some principles on how to analyze data under MNAR and look into the sensitivity of the analysis to the non-ignorability assumptions. The basis of such an analysis consists of constructing a model for the observed data distribution and the missing data mechanism. Estimate the model under MAR. Next isolate from this parameterization a sensitivity parameter. Such a parameter does not influence the fit of the model to the observed data, however it does influence the full-data model. Find a suitable prior for this parameter and incorporate the uncertainty of the missing data mechanism by averaging over the possible values of the sensitivity parameter.

The number of different situations that are treated is exhaustive: models for both continuous and bivariate longitudinal data and combinations thereof are handled, data collected at discrete-time points or at continuous time points, responses only or in combination with possibly missing (time-varying) covariates etc. The most popular factorizations of the complete data model are reviewed: selection models, pattern mixture models and shared parameter

models. Clearly the pattern mixture approach is most favoured by the authors.

Also they show how to compare the fit of different models by the deviance information criterion (DIC) and by posterior predictive checks.

The book starts with the introduction of several well-chosen examples coming from a variety of clinical trials handling schizophrenia, growth hormones in elderly, smoking cessation and HIV. Throughout the book these are repeatedly (re)analyzed using the different missing data paradigms that are explained during the course of the book. The consequences of the different assumptions on the missing data mechanism when analyzing these example data are clearly outlined.

The book has a rather high starting level. The authors assume reasonable familiarity with the subject matter, so the introduction is kept short. Nevertheless all necessary basics are introduced and accompanied notation is concisely described in the opening part of the book. Especially the part on Bayesian analysis, using the WinBugs software program and the use of MCMC is somewhat limited. Also the WinBugs syntax used for the analysis of the examples is lacking. So redoing the analyses is hard for readers lacking a solid background in using the WinBugs software. Most analyses in the book are confined to giving the results of the fit only. These are thoroughly explained, however. Only for some of the most advanced analyses under MNAR the syntax can be found on the website of one of the authors.

The book rounds up with a very exhaustive list of carefully chosen references.

This monograph is clearly written and figures and tables are to the point. The suggested notation is used consistently throughout the book which contributes greatly to the readability. In conclusion: I think this is an excellent book covering the current state in Bayesian modelling of missing data in longitudinal settings. It seems ideally suitable for researchers working on data with repeated measures and wanting to know more than just the basics and especially how to adopt Bayesian methods into this field. Because of its rather high entry level, it seems less suitable to serve as an introduction to this field.

This book is one of the first published books on the topic of adaptive design (AD) methodology in the field of clinical trials. It is published in the Chapman & Hall/CRC Biostatistics series “to provide useful reference books for researchers and scientists in academia, industry and government, and also to offer textbooks for undergraduate and/or graduate courses in the area of biostatistics.” The targeted audience of the book are “biostatisticians, medical researchers, pharmaceutical scientists, and reviewers in regulatory agencies, who are engaged in the areas of pharmaceutical research and development (quotes from the Series introduction, at the beginning of the book).

The specific objectives of the book, as stated by the authors in the preface are:

- “to provide a comprehensive and unified presentation of the principles and methodologies in adaptive design and analysis with respect to adaptations made to trial and/or statistical procedures based on accrued data of on-going clinical trials”,
- to “give a well balance summary of current regulatory perspectives and recently developed statistical methods in this area”
- and to “provide a complete, comprehensive, and updated reference and textbook in the area of adaptive design and analysis in clinical research and development”.

The book is organised in 12 chapters. Chapter 1. Introduction, defines what AD are, discusses regulatory perspectives, describes basic concepts and statistical considerations about AD and discusses practical issues related to the different kind of adaptive designs. The second chapter, Protocol Amendment, addresses the issue of the potential impact of amendments of the trial procedures on shifting the target population. The authors emphasize the risk that such shifts in target populations provoked by amendments may lead to a totally different clinical trial, unable to answer the scientific or medical questions it was intended to address. The third chapter, Adaptive Randomization, discusses, after an introductory section on conventional randomisation, the different types of adaptive randomisation: treatment-adaptive randomisation, covariate-adaptive randomisation and response-adaptive randomisation, the latter being particularly developed. Finally, issues related to adaptive randomisation: bias, impact on statistical inference and power and sample-size are discussed. Chapter 4, Adaptive Hypotheses, discusses adaptations to the clinical trial hypotheses: switch from a superiority hypothesis to a non-inferiority hypothesis, switch from a single hypothesis to a composite hypothesis or multiple hypotheses, change in hypotheses due to the switch in study endpoints, dropping ineffective arms, interchange between the null hypothesis and the alternative hypothesis. Only the switch from a superiority hypothesis to a non-inferiority hypothesis is developed in details. Chapter 5, Adaptive Dose-escalation trials, describes adaptive methods for dose selection in early phase studies, with a short section on continual reassessment methods and a more developed one on hybrid frequentist-Bayesian adaptive designs. Chapter 6, Adaptive group sequential design, is devoted to “classical” group

sequential designs. Adjustment of sample size without or with unblinding is covered in chapter 7, Adaptive sample size adjustment. The too short chapter 8 introduces Adaptive seamless phase II/III designs. Chapter 9, Adaptive treatment switching, covers the issue of patients switching treatment in time-to-event clinical trials. Bayesian methods for multiple-stage designs for single-arm trials and Bayesian optimal adaptive designs are discussed in chapter 10, Bayesian approach (Bayesian methods for dose escalation trials, were already covered in chapter 4). Clinical trial simulation as a tool to evaluate the performance of the adaptive designs foreseen at the time of designing the trial are presented in chapter 11, which also introduces the software ExpDesign Studio® dedicated to such clinical trial simulations. Examples of an adaptive group sequential design, a dose-escalation design and 4 examples of seamless phase II/III design trials are presented and discussed in chapter 12 Case studies.

As a biostatistician with a long experience in the field of clinical development but without a great expertise in adaptive/flexible designs, I had high expectations when I started reading this book. After having completed this reading, I must admit that I was quite disappointed. The book is sometimes confusing, and does not provide a clear and well-constructed view, ready to be put in practice, on adaptive designs. Some chapters are well written and sufficiently detailed, like, for example, chapter 3 on adaptive randomisation, whereas others, covering very important aspects of the field, are far too short and insufficiently developed. Chapter 8 on adaptive seamless phase II/III designs, is particularly frustrating with only 11 pages on this very important and fast evolving topic, which would have deserved a much longer development.

I must also point out the poor quality of the publishing: the book is flawed by many inaccuracies, misspelling, grammar mistakes, errors in references to equations, etc. To cite only a few of these mistakes : modifications of the design of an experiment (...) has been in practice for hundreds, if not thousands, of years in medical research (section 1.2, page 6), wrong description of the Randomized play the winner paradigm, where additional balls of the failing treatment (instead of the successful one) are added in the urn (section 3.4, page 59), wrong references to equations in chapter 5 and also chapter 7, independent p-volume (instead of p-value) p 137... The book has apparently lacked a careful final proof reading. These flaws, together with the highly mathematical content of some of the sections will render the book useless to beginners or readers without a strong mathematical/statistical expertise.

Despite its pitfalls, this book has the merit of being one of the first books available on this topic. One of its strength is its very rich list of references, which will be helpful to anyone trying to develop his knowledge in the field. In the absence of a better alternative, it can be recommended as an introductory reading to any statistician wishing to increase his knowledge on adaptive design methodology. Let us hope that a new edition, devoid of quality flaws and with enriched content in some chapters insufficiently developed and additional chapters on new methods developed since the publication of this first edition will soon be issued.

ISCB GENERAL INFORMATION

Advertising Rates

The prices are: Full A4 page: € 500 Half A4 page: € 300 Quarter A4 page: € 200	Additionally, we will include loose flyers with the distribution of the newsletter at an initial handling cost of € 500. However, if the addition of the flyers increases the postal charges, the advertiser will also be charged the difference in distribution costs. For further information, please contact the ISCB Office.
Publishing dates: Jun 2010 (and deadlines) Dec 2010	early May 2010 early Nov 2010
Adverts sent to the ISCB emailing list of approximately 900 current and recent members:	€ 750 for 4 emails/year € 300 for a single email
ISCB webpage advertising:	€ 750 for one year with Link from ISCB's homepage

IMPORTANT NOTE: Email Lists and Personal Information

ISCB has a strict policy not to give out any information concerning its members to any organisation which requests it. If a company wishes to send material to the members, the brochures must be sent to the Society's Permanent Office and News Editor for distribution with the News (see above). Alternatively, small non-commercial announcements can be sent free of charge as an email to most members of ISCB.

Society's Aims

The Society is organised and shall be operated for educational and scientific purposes with the following Aims:

- to stimulate research on the biostatistical principles and methodology used in clinical research;
- to increase the relevance of statistical theory to clinical medicine;
- to promote high and harmonised standards of statistical practice;
- to work with other societies and organisations in the advancement of biostatistics;
- to promote better understanding of the use and interpretation of biostatistics by the general public, and by national and international organisations and agencies within the public and commercial sectors with an interest in, and/or responsibilities for, public health; and
- to provide a common forum for clinicians and statisticians through meetings, seminars and publications

Changes of Address or Email

Please inform the Permanent Office that looks after the membership and mailing list databases. Also, if your email address changes, please inform the Office and the News Editor so that your address is changed in the ISCB database and emailing list (googlegroup).

Information on Submitting Articles

Articles sent via email (Word, HTML or text) on almost any topic are most welcome. This is an informal newsletter for you the readers, so please join in and make ISCB News a magazine that's even more interesting and fun to read.

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<p>Professor of Biostatistics and Chair of the Department of Medical Biometry and Informatics, Medical Faculty, Ruprecht-Karls-University, Heidelberg, Germany until 2007, now retired. Main activities are biostatistical consulting of clinical research and responsibility for the design, conduct and analysis of clinical trials. Methodological areas of interest are multiplicity problems in testing, heterogeneity in Meta-Analyses and flexible designs in clinical trials. I have served ISCB as an Executive Committee member since 2000, was Treasurer from 2003-06 and Vice President from 2007-2008. In 1999, I organised ISCB20 in Heidelberg. As President, I will try to enlarge the fields of activity of the society, and herewith to increase membership. I would like to make our meetings a discussion forum of all scientists involved in clinical and epidemiological research: Biostatisticians, trialists with medical background and epidemiologists.</p>				
Vice-President: Harbajan Chadha-Boreham	Actelion Pharmaceuticals Ltd, Department of Biometry, Gewerbestrasse 16, CH-4123 Allschwil, Switzerland	+41 61 565 66 69	+41 61 565 64 70	Harbajan.Chadha-Boreham@Actelion.Com
<p>Consultant Biostatistician in the Department of Biometry, Actelion Pharmaceuticals Ltd., Basel, Switzerland. My main activities in pharmaceutical statistics involve design, conduct, analysis and reporting of clinical trials and epidemiology studies across a variety of therapeutic areas. Current interests are focused on statistical methods for the evaluation of medical diagnostic tools and the evaluation of treatments for rare diseases. I joined the ISCB in 1993 and have been an active member of the Society; firstly as a member of the ISCB Subcommittee on Statistics in Regulatory Affairs and later as Chair of the Local Organising Committee of ISCB23 (2002) Conference held in Dijon, France. In 2003 I set up the ISCB Subcommittee on Conference Organising; we have developed the "Conference Organising Guidelines" to help the organisers of future conferences. Linked to Conference Organising, the Subcommittee has created facilities for storing documents from past conferences on the ISCB website. As a member of the recently formed ISCB Subcommittee on Membership, I have been involved in various initiatives for promoting our society to increase its membership. I have served on the ISCB Executive Committee for eight years; four years as an ordinary member and four years as Secretary, taking care of the quarterly teleconferences of the ExCom, the Annual ExCom and General Meetings. As Vice-President and Chair of the Conference Organising Subcommittee, I would facilitate exchange of experiences of the past and future organisers so that we can continue to offer ISCB Members annual meetings that have high scientific quality, are socially interesting and are financially successful. As a Member of the Subcommittee on Membership, I will help to step up our efforts to foster ISCB links with sister societies that are involved in clinical and epidemiological research.</p>				
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<p>Professor of biostatistics at the department of Clinical Epidemiology, Biostatistics and Bioinformatics at the Academic Medical Center of the University of Amsterdam in the Netherlands. I was trained as a mathematician and psychologist at the university of Groningen (the Netherlands) and obtained my PhD at the University of Nijmegen (the Netherlands). My thesis concerned consistency of estimators and goodness of fit tests of a variant of the random-effects logistic regression model. My biostatistical interests are amongst others statistical genetics, repeated measures and monitoring, clinical trials, and meta-analysis, and I was involved in numerous clinical trials and epidemiological research projects. I have been a member of ISCB for over 15 years, was member of the organising committee of the Leiden conference in 2004, and was a member of the ExCom for the period 2003-2006, and ISCB treasurer 2006-2008. As treasurer I would like to proceed to monitor the financial situation of the Society and help organizing successful scientific conferences that are sufficiently profitable to carry on the Society's work.</p>				
Secretary and News Editor: David W. Warne	Chemin du Petit-Bel-Air 115, CH-1226 Thônex, Switzerland	+41 22 700 63 80		david_w_warne@bluewin.ch
<p>Associate Director Biostatistics, Merck Serono, Geneva, Switzerland. My main activities in medical statistics involve designing clinical development projects, and the design, conduct, analysis and reporting of clinical trials in infertility. I am especially interested in non-inferiority and equivalence studies and in the practical aspects of clinical trials such as randomisation and use of Bayesian methods. I joined ISCB in 1992 as Newsletter Editor and have attended all the annual meetings from 1993 to 2008 and taken part in most of the Executive Committee meetings over the last 16 years. As well as editing 34 issues of the ISCB News, I was chair of the Communications Subcommittee from 1999-2007 and run the Society's emailing list. I have been a member of the Subcommittees on Conference Organising since 2004 and Membership since 2007. I was the chair of the Local Organising Committee of ISCB27 in Geneva in 2006. In 2007, I was honoured to be made a Life Member of ISCB. As Secretary, I look forward to continue helping with the organisational aspects of the Society and its annual meetings and, as an Officer of the ExCom, I would like to help ISCB maintain its reputation for providing highly successful annual meetings and courses.</p>				

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ISCB Membership and Googlegroups Emailing Lists

From Rita Schou (ISCB Office) and David W. Warne (Googlegroups Administrator)

We try to make sure our membership database (in Denmark) is kept up to date.

We also have an electronic mailing list called iscb@googlegroups.com, which allows members from the current and past years to be contacted to discuss statistical ideas and to receive news about ISCB events.

From time to time we compare the 2 databases and if we find you've got 2 email addresses, we'll ask which you prefer.

If you haven't done so already, please send us your email address to allow us to contact you more easily.

If you've sent us your email, but haven't accepted the invitation to join the [iscb googlegroup](#), please accept the next invitation by pressing Reply-Send.

Rest assured that no company will send you any junk email – all emails are checked by the Office or the Googlegroup Administrator.

ISCB Subcommittees: Contact Details

Please contact the chairs/secretaries of these subcommittees for further information.

(*=President's Representative)

Title & Email	Terms of Reference	Members	Email addresses
Conference Organising iscb-conf-org@ googlegroups.com	1. Bring together ISCB conference organisers or ISCB members who have an interest in sharing and passing on their knowledge and experience to help future ISCB conference organisers. 2. Document processes and systems for assisting ISCB conference organisers. 3. Review and update the documents whenever necessary and promote their usage for improving the procedures or meetings.	Chair:	
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12. Koos Zwinderman (NL)	a.h.zwinderman@amc.uva.nl		
Education iscb-education@ googlegroups.com	To support and organise one or two day courses on contemporary methods in clinical biostatistics in locations represented by the Society. Guidelines and a list of courses offered in the past are available.	Chair:	
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		10. *Norbert Victor (D)	victor@imbi.uni-heidelberg.de
Epidemiology iscb-epidemiology@ googlegroups.com	1. Advise the Scientific Programme Committee of the annual ISCB meetings, if needed, on relevant topics in epidemiology for establishing invited sessions and choosing invited speakers. 2. Establish connections with Epidemiological Societies and organise mutual sessions, courses or workshops at our conferences or elsewhere. 3. Generate awareness and discussions in the Society of guidelines for conducting, analysing and reporting epidemiological studies.	Chair:	
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13. Stephen Walter (CDN)	walter@mcmaster.ca		
National Groups Isccb-national-groups@ googlegroups.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. 4. The Subcommittee administers the Conference Awards for Scientists for the annual ISCB meetings.	Chair:	
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How to Contact the ISCB Subcommittees (continued)

Title & Email	Terms of Reference	Members	Email addresses
<p>Membership</p> <p>iscb-membership@googlegroups.com</p>	<p>To explore strategies to increase the ISCB membership by means of:</p> <ol style="list-style-type: none"> 1. Highlighting the unique position of the ISCB, i.e. bringing together clinicians, methodologists, epidemiologists and biostatisticians 2. Make strategic links with medical and epidemiological societies in order to make publicity at their meetings and bring clinicians/epidemiologists with a methodological/biostatistical interest to our ISCB meeting 3. Widen the geographical spread of the ISCB members 4. Ensure the regeneration of our current core membership. 5. Provide guidelines for future conference organisers on choosing a scientific programme committee that will help in widening membership 6. To consider the future of the Newsletter, including ways to support the Editor, procedures for transition of editorship. 7. To maintain the ISCB homepage on the World Wide Web and facilitate placement of annual meeting information on the homepage. 8. To consider other communications with members, such as through email or the World Wide Web. 	<p>Chair:</p> <p>1. Emmanuel Lesaffre (B)</p>	<p>emmanuel.Lesaffre@med.kuleuven.be</p>
		<p>Secretary:</p> <p>2. KyungMann Kim (USA)</p>	<p>kmkim@ biostat.wisc.edu</p>
		<p>Members:</p> <p>3. Michal Abrahamowicz (CDN)</p>	<p>michal@ epimgh.mcgill.ca</p>
		<p>4. Lucinda Billingham (UK)</p>	<p>L.J.Billingham@ bham.ac.uk</p>
		<p>5. Bjarne Bodin (DK)</p>	<p>bbo@ Cyncron.com</p>
		<p>6. Harbajan Chadha-Boreham (CH)</p>	<p>Harbajan.Chadha-Boreham@ Actelion.Com</p>
		<p>7. Toshiro Tango (JPN)</p>	<p>tango@ niph.go.jp</p>
		<p>8. Maria Grazia Valsecchi (I)</p>	<p>grazia.valsecchi@ unimib.it</p>
		<p>9. Giota Touloumi (GR)</p>	<p>gtouloum@ med.uoa.gr</p>
		<p>10. *Norbert Victor (D)</p>	<p>victor@ imbi.uni-heidelberg.de</p>
		<p>11. David W. Warne (CH)</p>	<p>david_w_warne@ bluewin.ch</p>
<p>Statistics in Regulatory Affairs</p> <p>iscb-reg-aff@googlegroups.com</p>	<p>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/her absence, the Vice-President.</p>	<p>Chair:</p> <p>1. Christoph Gerlinger (D)</p>	<p>christoph.gerlinger@ bayerhealthcare.com</p>
		<p>Secretary:</p>	
		<p>Members:</p> <p>2. *Harbajan Chadha-Boreham (CH)</p>	<p>Harbajan.Chadha-Boreham@ Actelion.Com</p>
		<p>3. Lutz Edler (D)</p>	<p>edler@ dkfz-heidelberg.de</p>
		<p>4. Tim Friede (UK)</p>	<p>T.Friede@ warwick.ac.uk</p>
		<p>5. Christos Nakas (GR)</p>	<p>cnakas@ gmail.com</p>
		<p>6. Jen-Pei Liu (TW)</p>	<p>jpliu@ ntu.edu.tw</p>
		<p>7. Martin Schumacher (D)</p>	<p>ms@ imbi.uni-freiburg.de</p>
		<p>8. Jørgen Seldrup (F)</p>	<p>Jorgen.seldrup@ quintiles.com</p>
<p>Student Conference Awards</p> <p>iscb-stud-conf-awrd@googlegroups.com</p>	<p>Student conference awards are available for registered postgraduate students to attend the annual conference and present a paper. The Subcommittee shall receive submissions, judge them, and administer the awards. The rules and procedures are announced in a timely issue of the Newsletter and on the ISCB annual conference webpage.</p>	<p>Chair:</p> <p>1. KyungMann Kim (USA)</p>	<p>kmkim@ biostat.wisc.edu</p>
		<p>Secretary:</p>	
		<p>Members:</p> <p>2. Carl-Fredrik Burman (S)</p>	<p>carl-fredrik.burman@ astrazeneca.com</p>
		<p>3. *Emmanuel Lesaffre (B)</p>	<p>emmanuel.Lesaffre@ med.kuleuven.be</p>
		<p>4. Ulrich Mansmann (D)</p>	<p>mansmann@ ibe.med.uni-muenchen.de</p>
		<p>5. Vana Sypsa (GR)</p>	<p>vsipsa@ cc.uoa.gr</p>
		<p>6. Jean-Christophe Thalabard (F)</p>	<p>jean-christophe.thalabard@ htd.aphp.fr</p>
<p>Vaccines</p> <p>iscb-vaccines@googlegroups.com</p> <p>Please see www.iscb-vaccines.info</p>	<ol style="list-style-type: none"> 1. Create a professional platform for statisticians active in the research on vaccines. 2. Discuss new regulatory guidelines and comment upon draft guidelines, in collaboration with the subcommittee on Statistics in Regulatory Affairs. 3. Keep up-to-date, discuss, apply and encourage relevant statistical and methodological developments. 4. Encourage professional development. 5. Organize symposia in the annual ISCB meetings or in collaboration with ISCB on methodological developments in vaccines research. 	<p>Chair:</p> <p>1. Jos Nauta (NL)</p>	<p>jos.nauta@ solvay.com</p>
		<p>Secretary:</p> <p>2. Jingyee Kou (USA)</p>	<p>jingyee.kou@ fda.hhs.gov</p>
		<p>Members:</p> <p>3. Andrew Dunning (USA)</p>	<p>andrew.dunning@ sanofipasteur.com</p>
		<p>4. Allen Izu (USA)</p>	<p>allen.izu@ novartis.com</p>
		<p>5. Marc Fourneau (B)</p>	<p>marc.fourneau@ gskbio.com</p>
		<p>6. Jukka Jokinen (SF)</p>	<p>Jukka.Jokinen@ thl.fi</p>
		<p>7. Ivan Chan (USA)</p>	<p>ivan_chan@ merck.com</p>
		<p>8. Lawrence Moulton (USA)</p>	<p>lmoulton@ jhsph.edu</p>
		<p>9. Julia Singer (A)</p>	<p>julia_singer@ baxter.com</p>
		<p>10. *Koos Zwinderman (NL)</p>	<p>a.h.zwinderman@ amc.uva.nl</p>

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.

Meetings in recent years have been held in Leiden (2004), Szeged (2005), Geneva (2006), Alexandroupolis (2007), Copenhagen (2008) and Prague (2009). The next meeting will be held in Montpellier (2010). 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.



The composition of the Executive Committee (ExCom) for 2010 is as follows:

Officers:

President: Norbert Victor (D),
Vice-President: Harbajan Chadha-Boreham (CH),
Treasurer: Koos Zwinderman (NL),
Secretary/: David W. Warne (CH),
News Editor

Members:

Webmaster: Bjarne Bodin (DK),
Members: Lucinda Billingham (UK),
Krisztina Boda (Hungary),
Adriano Decarli (Italy),
Lutz Edler (Germany),
KyungMann Kim (USA),
Ulrich Mansmann (Germany),
Jean-Christophe Thalabard (France),
Giota Touloumi (Greece).

The Annual General Meeting of the ISCB is organised to coincide with the scientific meeting. Membership of the Society is drawn from around 40 countries worldwide and the number of members is about 900.



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



The Society publishes a Newsletter twice a year. The ISCB News editor is David W. Warne, Chemin du Petit-Bel-Air 115, CH-1226 Thônex, 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 2010) Ordinary membership fee is €40. The Full-time Student Membership fee is €20.


Applications for membership should be sent to:

ISCB Permanent Office,
PO Box 130,
Teglgaarden 60,
DK-3460 Birkerød, Denmark

Tel: +45 4214 6279
Fax: +45 7022 1571
email: office@iscb.info
www: www.iscb.info

INTERNATIONAL SOCIETY FOR CLINICAL BIOSTATISTICS

2010 Membership Subscription

Surname: _____		First name: _____	
Title (Prof/Dr/etc): _____		Post held: _____	
Institute/Company: _____			
Address: _____ _____			
Post code and country: _____			
Phone No.: _____		E-mail: _____	
Fax No.: _____		Please provide your email address as it will be used to send you the ISCB News in the future.	
SUBSCRIPTION:			
<input type="checkbox"/>		Ordinary membership of ISCB (to 31 December 2010):	€(EUR) 40.00
(please tick one only)		<input type="checkbox"/>	Full-time Student Membership of ISCB (to 31 Dec. 2010): €(EUR) 20.00 (students should provide a letter from their supervisor or head of department)
Have you previously been a member of ISCB? <input type="checkbox"/> Yes <input type="checkbox"/> No			
PAYMENT IS MADE BY:			
Credit Card Authorisation: <input type="checkbox"/> VISA <input type="checkbox"/> Master Card <input type="checkbox"/> Euro Card <input type="checkbox"/> JCB			
Signature: _____		Date: _____	
Your name on the credit card:	Card number to debit (16 digits):	Validation code (3 digits) CVC/CVV:	Expiry date (MM/YY):
_____	_____	_____	_____
Cheque/Money Order:			
<input type="checkbox"/> A cheque made payable in € – drawn on a bank in the United Kingdom			
<input type="checkbox"/> A Money Order			
Cheque / Money Order No. (if known): _____		Date sent: _____	
Cheques must be made payable to the <i>International Society for Clinical Biostatistics</i> and returned with this form to the Permanent Office address. <i>Note: Non-Euro cheques, bank cheques not drawn on a UK bank, and cheques not made payable to ISCB will be returned.</i>			
Bank Transfer:			
Please transfer direct to:		<input type="checkbox"/>	
Barclays Bank plc	PO Box 69	Euro Account No.	6687 4511
121 Queen Street	Cardiff CF1 1SG	Bank Sort Code:	20-18-15
UK		IBAN:	GB28 BARC 2018 1566 8745 11
		SWIFT/BIC:	BARCGB22
Please return this form either by e-mail to: office@iscb.info			
or by post to: ISCB Permanent Office PO Box 130 Teglgaarden 60 DK-3460 Birkerød Denmark			
Tel: +45 4214 6279			
Fax: +45 7022 1571			

Calendar

29 August – 02 September 2010

Montpellier, France

ISCB31

Info: web: www.iscb2010.info, email: iscb2010@alphavisa.com



ISCB is affiliated to ISI. For the latest conference information, see: isi.cbs.nl/calendar.htm



February 1 - 4	<i>Statistical Modelling and Inference Conference</i> to celebrate Murray Aitkin's 70 th birthday. Location: QUT Gardens Point Campus, Brisbane, Queensland, Australia Website: www.aitkinconference.scitech.qut.edu.au	August 22 - 27	<i>The 19th Symposium of the European Regional Section of the IASC, COMPSTAT 2010</i> , to be held in the premises of Conservatoire National des Arts et Métiers (CNAM) in Paris. Deadline for contributed paper submission: January 10, 2010. E-mail: info@compstat2010.fr Website: http://www.compstat2010.fr
March 10 - 12	<i>Joint UNECE / Eurostat / OECD Work Session on Statistical Metadata</i> . The Work Session will be held at the Palais des Nations, Avenue de la Paix, Geneva, Switzerland. The aim is to exchange experience among experts and to identify best practices in the field of statistical metadata. The Work Session will focus on progress under the different parts of the Common Metadata Framework (CMF) initiative (http://www1.unece.org/stat/platform/display/metis/) Information: Mr. Steven Vale, Statistical Division, UNECE Phone: +41-22 917 32 85 Fax: +41-22 917 00 40 E-mail: steven.vale@unece.org Website: www.unece.org/stats/documents/2010.03.metis.htm	August 29 - September 2	<i>The 31st Annual Conference of the International Society for Clinical Biostatistics</i> will be held at the ENSAM in Montpellier, France. It will bring together leading experts in the field of biostatistics with focus on changes concerning widely used methodologies. Special emphasis will be placed on Public Health Decision Making, Chronic Disease Modelling and Vaccination. The invited sessions include Novel approaches to clinical trials, Epidemiology, Analysis of complex data and Use of genetic data. Contact information: Ladret Véronique and Castelli Christel E-mail: contact@iscb2010.info
May 9 - 12	<i>Workshop on Statistical Modelling: Challenges in Health</i> to be held in Lisbon, Portugal. The workshop aims to bring researchers interested in advanced statistical applications in Health challenging problems, to promote knowledge and experience exchange and also to encourage cooperation between the participants. Non-parallel sessions will include the following areas: health spatial problems, survival analysis, genetics, molecular biology, bioinformatics, latent class models in health. Information: Valeska Andreozzi Phone: +351 21 750 0170 E-mail: wstam2010@gmail.com Website: stam2010.fc.ul.pt	September 12 - 15	<i>SAMSI: 2010-11 Program on Analysis of Object Oriented Data Tutorials and Opening Workshop</i> , to be held in the Research Triangle Park, NC. Modern science is generating a need to understand, and statistically analyze, populations of increasingly complex types. The term "Analysis of Object Oriented Data" (AOOD) is aimed at encompassing a broad array of such methods. Examples include images, shapes of objects in 3D, points on a manifold, tree structured objects, and various types of movies. Information: Terri Nida, 919-685-9350 (phone) 919-685-9360 (fax) Website: http://www.samsi.info
May 23 - 26	<i>38th Annual Meeting of the Statistical Society of Canada</i> , Quebec City, Quebec, Canada. This conference will bring together academic, governmental and industrial researchers as well as users of statistics and probability and will feature workshops, invited and contributed sessions in all areas of statistics and probability. Information: Local Arrangements Chair- Thierry Duchesne Phone: +1 (418) 656-2131 x 5077 Fax: +1 (418) 656-2817 E-mail: duchesne@mat.ulaval.ca	September 14 - 17	<i>2010 Annual Meeting of the German Statistical Society</i> To be held in Nuremberg, Germany. Major topics: Energy, Research on Poverty Measurement, and Jump Regression Analysis. Gumbel lecture on „On the Asymptotic Size of Testing Procedures“ . Young researchers mini-symposium on "Microeconometrics: Theory and Applications". Special sections include: Effect of Model Selection on Subsequent Inference, Statistics of dynamic processes, Environmetrics, Change-Points, Risk Management. Information: Deutsche Statistische Gesellschaft Geschäftsstelle an der Helmut-Schmidt-Universität 22039 Hamburg Phone: +49- 40 65412779 Fax: +49- 40 65412565 E-mail: post@dstatg.de Website: www.statistische-woche-nuernberg-2010.de
July 5 - 8	<i>5th International Workshop on Applied Probability (IWAP 2010)</i> to be held at the north campus of Universidad Carlos III de Madrid in Colmenarejo, Madrid, Spain. The aim of this workshop is to bring together and foster collaboration among scientists engaged in applied probability. A wide range of active research fields will be covered featuring seven invited plenary lectures, presented by leading specialists, a large variety of invited sessions, contributed talks, and a special poster session. Contact: Fundacion Universidad Carlos III Address: Av. Universidad, 30, 28911, Leganes - Madrid Phone: +34 91 6249145 / 42 E-mail: congrega@fund.uc3m.es Website: www.est.uc3m.es/iwap2010	December 6 - 10	<i>Australian Statistical Conference 2010</i> . Place: Esplanade Hotel, Fremantle, Western Australia. Delegates from all areas of statistics will be able to communicate and join world class Australian and international statisticians to discuss new work and developments and share their knowledge and expertise. The theme: 'Statistics in the West: understanding our world', provides for presentations on a wide range of topics and recognises the role statistics plays in all aspects of life. Information: Promaco Conventions Pty Ltd P.O. Box 890, Canning Bridge, Western Australia 6153 Phone: +61 8 9332 2900 Fax: +61 8 9332 2911 E-mail: promaco@promaco.com.au Website: http://www.statsoc.org.au/statistical-conference.htm
July 5 - 9	<i>The 25th International Workshop on Statistical Modelling (IWSM 2010)</i> will be held at The University of Glasgow in Scotland from 5 th -9 th July 2010, with a short course on 4 th July 2010. The IWSM is an annual international workshop to promote and develop the use of statistical modelling in research and applications. Information: Claire Ferguson (claire@stats.gla.ac.uk) or Adrian Bowman (adrian@stats.gla.ac.uk). Website: www.stats.gla.ac.uk/IWSM2010		
July 11 - 16	<i>ICOTS 8 - Data and Context in Statistics Education: Towards an Evidence-Based Society</i> - to be held in the Ljubljana Cultural and Congress Centre at Cankarjev Dom, Ljubljana, Slovenia. Contributed Paper Sessions will be arranged in a variety of areas. It is being organised by the IASE and the Slovenian Statistical Association. Those interested in submitting an invited paper should contact the appropriate Session Organiser before 1 st December 2008. Contributed paper sessions will be arranged in a variety of areas. Those interested in submitting a contributed paper should contact either Gilberte Schuyten, John McKenzie or Flavia Jolliffe before 1 st September 2009. Posters: Those interested in submitting a poster should contact Mojca Bavdaz or Alesa Lotric Dolinar before 15 th January 2010. Information: ICOTS IPC Chair John Harraway Programme Chair, Roxy Peck Scientific Secretary, Helen MacGillivray Website: http://ICOTS8.org		
July 31 - August 5	<i>2010 Joint Statistical Meetings</i> . Canada. To be held at the Vancouver Convention Center, Vancouver, British Columbia. Website: http://www.amstat.org/meetings/jsm/2010/index.cfm		
August 17 - 22	<i>The 28th European Meeting of Statisticians</i> , to be held in Piraeus (Greece). Under the auspices of the European Regional Committee of the Bernoulli Society		