

International Society for Clinical Biostatistics

News

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Executive Committee 1996/97

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Editorial

Four years have gone by since I took on the job of ISCB News Editor, and that period has been one of stability in the Executive Committee, with several members and officers serving 2 terms of 2 years. But now, we have a fresh set of faces to take ISCB through the next 2 or 4 years. We also have a new, long-awaited, and much-praised constitution to guide us there.

After heading East in 1996 for a wonderfully successful and enjoyable meeting in Budapest, ISCB goes West in 1997, across the Atlantic for the first time to Boston, USA, for a joint meeting with the Society for Clinical Trials. This should be an excellent conference bringing together the 2 societies who contribute much to the 2 leading Medical Statistics journals, *Statistics in Medicine* and *Controlled Clinical Trials*.

What are my hopes for ISCB News ? I would welcome so much some articles from round the world: what do ISCB members do in Australia, New Zealand, Sweden... ?

Thanks to the contributors to this News: Karsten Schmidt, Simon Day, Nancy Geller, Jørgen Seldrup, Marc Buyse, Helmut Schäfer, Mike Campbell, Wolfgang Köpcke, Andrew Lawson, Rick Chappell, Stephen Senn, and Guernsey McPearson, and Skip Olson for proof-reading it.

Note that it is planned to publish ISCB News 3 times in 1997, in April, August and December. Deadlines are the end of March, July and November.

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ISCB Membership

Once again we welcomed many new (85) and former (56) members at the ISCB conference in Budapest. The number of countries now stands at a record 34 !

	Maastricht		Brussels		Cambridge		Basel		Barcelona		Budapest	
	ISCB10		ISCB12		ISCB14		ISCB15		ISCB16		ISCB17	
	Sep89	end89	Jul91	end92	Sep93	Dec93	Jul94	Dec94	Jul95	Dec95	Jul96	Dec96
Total	276	261	859	596	377	715	305	698	425	725	283	702
# Countries	19	23	30	32	27	32	22	31	30	33	26	34
# Country												
1 UK	33	50	86	90	128	176	51	120	98	144	44	121
2 Germany	39	30	80	67	39	75	42	84	23	71	35	78
3 France	29	30	78	52	26	62	21	50	46	73	29	67
4 Sweden	14	23	37	51	22	53	20	54	37	58	19	64
5 USA	13	18	227	45	16	40	14	39	25	41	21	40
6 Italy	11	16	47	33	23	37	8	32	13	32	18	33
7 Belgium	5	13	99	22	13	27	13	30	14	30	8	32
8 Denmark	3	4	14	58	23	38	8	31	16	30	11	32
9 Poland	1		3	11	2	11	4	24	2	24	7	30
10 Netherlands	94	14	46	30	23	38	22	33	23	36	10	29
11 Switzerland	10	14	24	25	8	22	68	80	14	33	10	29
12 Hungary		1	4	21	1	17	4	18	6	19	25	25
13 Spain		10	14	12	9	18	6	12	71	46	7	23
14 Norway	4	13	17	18	10	25	3	22	3	12	10	18
15 Austria	7	4	4	9	6	11	6	13	4	11	9	16
16 Canada	3	6	35	12	5	14	6	14	4	11	4	13
17 Finland	3	2	4	7	4	7	2	9	3	9	2	9
18 Australia	2	6	12	9	2	11		6	3	9		8
19 Ireland	1	1	1	2	1	3		4	4	3	1	4
20 Israel		1	3	3	3	4	3	4	1	4	3	4
21 Japan	3	2	10	6	4	7	1	5	2	7		4
22 Hong Kong				1		1		2	2	3	1	3
23 Russia									1	1	2	3
24 Portugal		1	4	3	2	5		2		2		2
25 South Africa				1	3	4		1	1	3		2
26 New Zealand				1			1	1			2	2
27 Romania											2	2
28 Czech. Rep.							1	1		1		1
29 India	1		1	1		1		1		1		1
30 Malaysia										2		1
31 Slovenia			1	1	1	2	1	3	1	2	1	1
32 China				1	1	1		1		1		1
33 Thailand			2	1		1			1	1	1	1
34 Iran									1		1	1
35 Mexico			1									1
36 South Korea									3	3		
37 Brazil									2	2		
38 Cuba									1			
39 Greece				1	1	1	1	1				
40 Zimbabwe								1				
41 Kenya			2	1	1	1						
42 Turkey			1	1		1						
43 Columbia			1									
44 Philippines			1									
45 Kuwait		1										
46 Oman		1										

When looking at the professional occupations of our 702 members, as indicated on the subscription form, it is seen that 403 are statisticians, 19 medical doctors, 39 both of these, 16 neither and 225 are "unknown". Perhaps a more accurate picture can be drawn if you unknowns could fill in the box on the 1997 subscription invoice ?

by Karsten Schmidt

Two events in the history of ISCB seem to augur a new era of the Society. One event is the adoption of the new Constitution at the AGM this year in Budapest, giving a much more firm framework for the work of the Society. We shall have elections by postal ballot, approval of subcommittees at the General Meeting, and auditing of accounts by professionals just to mention a few enhancements. The other event to come is the next Annual Meeting (joint meeting with the Society for Clinical Trials) to take place for the first time outside Europe from 6-10 July 1997 in Boston, USA, showing a movement towards true internationalisation.

From my own experience and the messages I have got from various attendees, the Annual Meeting in Budapest certainly was a success with respect to the organisation and the scientific programme. For reasons I do not completely understand the number of attendees was somewhat less than at previous meetings. This could have entailed a financial loss. However, it has now turned out that we actually have a profit of about 17,000 £ and 141 new members; thus, a financial success as well. With its present strong economy ISCB is prepared if the Boston meeting should give a loss, which I doubt will happen. Even if the number of ISCB members attending the Boston meeting should be much less than expected, the financial consequence is not to be feared. However, the consequence for the future activities as an international society would be jeopardised. Therefore, I encourage all members to persist, although it may be difficult because many organisations fund meetings in Europe more easily than across the Atlantic, which is not rational since the travelling cost within Europe may be as high as to USA.

At their first meeting in Budapest the Executive Committee established four subcommittees as appears from another column in these News. Two of them continue previous work on statistics and Statisticians in Regulatory Affairs, respectively, whereas two start up new activities. In particular the subcommittee on Education may come up with recommendations that will extend the society's more regular activities beyond those directly connected to the annual meetings, a development that I believe is desirable.



Minutes of the 1996 Annual General Meeting

from Stephen Senn

Venue: Semmelweiss University, Budapest, Hungary, 27 August 1996

In the chair: M Buyse (President), **Taking the minutes:** SJ Senn (Secretary), **Present:**

AL Johnson	UK	N Bossard	France
CR Palmer	UK	LR Salmi	France
B Hajtman	Hungary	JC Thalabard	France
D Altman	UK	S Fritsch	Austria
A Zielinski	Poland	SC Todd	UK
H Stanuch	Poland	G Nicholls	UK
M Bienkiewicz	Poland	RML Whitlock	NZ
W Kupsc	Poland	H Wiemann	Germany
E Kawalec	Poland	V Hars	USA
M Demczuk	Poland	V Fidler	NL
N Geller	US	L Edler	Germany
A Lawson	UK	K Lovas	Hungary
GM Jacques	USA	A Nardi	Italy
B Nielsen	DK	H Tuchler	Austria
SJ Wiklund	Sweden	A Kaider	Austria
S Day	UK	G Heinze	Austria
J Hutton	UK	J Stare	Slovenia
D Warne	CH	H Heinzl	Austria
DM Berridge	UK	I Gathmann	CH
K Bodu	Hungary	A Benner	Germany
F Singer	Hungary	ML Blaga	Rumania
I Janosi	Hungary	T Postelnicu	Rumania
P Vargha	Hungary	P Reitmeir	Germany
E Dinya	Hungary	J Windeler	Germany
A Kandra	CH	MG Valsecchi	Italy
E Wehrle	CH	A Liberati	Italy
IJ Christensen	DK	BN Cesana	Italy
I Pazonyi	Hungary	P Barbetta	Italy
Z Kovacs	Hungary	A Polli	Italy
M Perera Chang	Hungary	S Mariotti	Italy
A. Heinecke	Germany	G Gallus	Italy
W Koepcke	Germany	A Hinke	Germany
R. van Strik	NL	M Schemper	Austria
J Seldrup	France	E Gehan	USA
P Mulder	NL	E Marubini	Italy
T Stijnen	NL	C Klersy	Italy
W Schaasberg	NL	K Schmidt	DK
CF Contant	USA	D Signorini	UK
G Raab	UK	R Prescott	UK
R Holle	Germany	I Guggenmoos-Holzmann	Germany
DO Dixon	USA	FW Rockhold	USA
FE Harrell Jr.	USA	R Mowery	USA
A Rajaeefard	IRAN		

Apologies for absence: B Huitfeldt, Treasurer, sent apologies that due to his presence on an EFSPi working party he was unable to attend the meeting. K Schmidt (Vice-President) would present the Treasurer's report on his behalf.

Matters Arising from ISCB16: The President drew attention to the financial statement which had been published in the Newsletter. This showed a profit of £15,000.

President's Report: The president mentioned the importance of this meeting in that the new constitution would be presented for approval. He listed proposed venues for future meetings of ISCB: Boston USA, 1997 (joint with the Society for Clinical Trials), Dundee, Scotland-UK, 1998, Heidelberg, Germany, 1999 and Trento, Italy, 2000. In the future the Society would move towards being a more professional organisation and would employ professional auditors for the accounts. The society now had a home page on 'the web'.

Secretary's Report: The secretary reported a quiet year. He pointed out that most of the work was undertaken by the permanent office and thanked Karsten Schmidt for his support.

Treasurer's Report. On Bernhard Huitfeldt's behalf, Karsten Schmidt presented the balance of the accounts which stand at £140,000. The ExCom did not propose to raise the membership fee for the moment but KS pointed out that the increased charges for postal ballots under the new constitution (if approved) would mean that fees would not cover costs. The arrangement regarding Statistics in Medicine with John Wiley was raised and A Johnson asked whether ISCB or Wiley paid for currency transactions (exchange charges) for this account. This was not clear.

Minutes of the 1996 Annual General Meeting (continued)

Newsletter. No points were raised for discussion.

Regulatory affairs. A letter of support for EFSPi comments on ICH E8 had been sent. These comments had been taken up by the CPMP. Wolfgang Koepcke gave a short history of SEDREG. A concluding report will be issued soon and SEDREG will be wound up.

Elections to the Committee. Nancy Geller was elected unopposed for the position of Vice-President. Simon Day was elected unopposed to the position of secretary. Bernhard Huitfeldt was re-elected unopposed to the post of treasurer. There were nine candidates for six places on the committee. After a ballot, Michael Campbell, Bruno Cesana, Ted Colton, Michael Schemper, Jorgen Seldrup and John Whitehead were elected.

Appointment of auditors. Suzanne Moeller was appointed as auditor to the Society again. A professional auditor will audit the accounts of Budapest ISCB17.

Constitution. Tony Johnson, the chief author of the new constitution, presented the history of the constitution and the most important new amendments. A motion from the Executive Committee proposing adoption of the constitution was then put to the vote and accepted unanimously by the meeting.

Future Meetings. Details of next year's meeting in Boston were presented by Nancy Geller and Frank Rockhold. Brief statements were made describing preparations for Dundee by Andrew Lawson, Heidelberg by Jurgen Windeler and Trento by Maria Valsecchi.

Close of the meeting. Marc Buyse closed the meeting by calling on members of the Society to meet again in Boston.

Random Harvest

*Eighth helping of the muesli of quotations
by Guernsey McPearson*

Random effects?

...when the usual symptoms of health or sickness disappoint our expectation; when medicines operate not with their wonted powers; when irregular events follow from any particular cause; the philosopher and physician are not surprised at the matter, nor are ever tempted to deny, in general, the necessity and uniformity of those principles by which the animal economy is conducted. They know that a human body is a mighty complicated matter, that many secret powers lurk in it, which are to us altogether beyond our comprehension...

David Hume, *An Enquiry Concerning Human Understanding*

Obviously a statistician.

A weaker man might be moved to re-examine his faith, if in nothing else at least in the law of probability.

Tom Stoppard, *Rosencrantz and Guildenstern are Dead*

The meta-analysts motto?

A wheen o' mickles maks a muckle

Scottish proverb

A warning to generic companies wishing to prove bioequivalence?

'You can't really say "similar" if it's the same again you want. "Similar" means something different.'

Anthony Burgess, *Enderby Outside*

A non-monotonic dose-response.

*A little Learning is a dang'rous Thing;
Drink deep, or taste not the Pierian Spring
There shallow Draughts intoxicate the Brain
And drinking largely sobers us again*

Pope, *An Essay on Criticism*

Missing not at random!

Met with Hadley, our Clerke, who upon my asking how the plague goes, he told me it encreases much, and much in our parish: "For", says he, "there died nine this week, though I have returned but six" - which is a very ill practice and makes me think it is so in other places and therefore the plague much greater than people take it to be.

Samuel Pepys, *Diary*, 30 August 1665

And this two centuries before the famous paper by Neyman and Pearson!

My father, whose way was to force every event in nature into an hypothesis, by which rate never man crucified TRUTH at the rate he did.

Laurence Sterne, *Tristram Shandy*

Extreme devotees of randomisation?

..every free man automatically participated in the sacred drawings, which took place in the labyrinths of the god every sixty nights and which determined his destiny until the next drawing.

Jorge Luis Borges, *The Lottery in Babylon*

ISCB Subcommittees

Please contact the chairmen of these subcommittees for further information.

Title	Terms of Reference	Members
SEDREG (Statistics in European Drug Regulation)	<p>The terms of references and function for the SEDREG Subcommittee is to finalize as soon as possible the position paper being prepared by the former Executive Team members. A final edition of the paper approved by the Committee must be available before the end of 1996 at which time the Subcommittee should be disabled.</p>	<p>The Subcommittee is chaired by Prof. Wolfgang Köpcke of the University of Münster (Germany), Prof. David Jones of the University of Leicester (UK) serves as Secretary, and Dr. Bernhard Huitfeldt of Astra Arcus AB (Sweden) and ISCB's President Dr. Karsten Schmidt of Spadille Biostatistics ApS (Denmark) are members.</p>
Fraud	<p>The Subcommittee on fraud will have the following goals:</p> <ol style="list-style-type: none"> 1. to investigate the role of biostatistics in the prevention and detection of fraud in clinical research, and 2. to promote the role of appropriate biostatistical contributions in the assessment of misconduct. <p>The Subcommittee will produce a position paper reflecting the opinions of its members. A manuscript will be available prior to, or at the next meeting of, the ISCB.</p> <p>The Subcommittee will coordinate its efforts with those of the Society for Clinical Trials, which is developing a paper on data integrity.</p> <p>The name of the Subcommittee may have to be changed as a result of its deliberations, as the term "fraud" may have legal implications.</p>	<p>Chair: Dr Marc Buyse, Brussels (Belgium), Secretary: Dr Jane L. Hutton, Newcastle upon Tyne (UK), Dr Lutz Edler, Heidelberg (Germany), Prof. Stephan Evans, London (UK), Dr Nancy Geller, Bethesda (USA), Prof. Stephen L. George, Durham (USA), Prof. Emmanuel Lesaffre, Leuven (Belgium), Prof. Gordon Murray, Glasgow (UK), Dr Jonas Ranstam, Lund (Sweden), Dr Bruno Scherrer, Fresnes (France)</p>
Statistics in Regulatory Affairs	<p>The subcommittee on Statistics in Regulatory Affairs will consider and influence the development of regulatory requirements, guidelines and other documents concerning the scientific aspects of data collection, management, analysis, and reporting. Also the Subcommittee will work on issuing new guidelines on these topics, where it is needed.</p> <p>The Subcommittee will serve for four years at which time its existence may be reapproved subject to clause 7.08 of article 7 in the Constitution.</p>	<p>The Subcommittee is chaired by Prof. Helmut Schäfer of Institute of Medical Biometry, Marburg (Germany), Prof. Stephen Senn of University College London (UK) serves as Secretary, and Dr. Jørgen Selstrup of Quintiles S.A. Strasbourg (France), and ISCB's President, Dr. Karsten Schmidt of Spadille Biostatistics ApS (Denmark), are members.</p>
Education	<p>The subcommittee on Education will assess the feasibility of organising a one or two day course on contemporary methods in Clinical Biostatistics which will involve several members as lecturers and be presented in locations represented by the Society. This includes assessment of costs and organisation of such a course. Once feasibility has been assessed, this subcommittee will be responsible for planning the course curriculum and selecting lecturers. The financial role of ISCB should be considered. The sub-committee will also receive requests from members that this course be given at their location and evaluate them. It is anticipated that the first site at which the course will be presented is Barcelona, Spain.</p>	<p>Chairman: Dr Mike Campbell (UK)</p>



ISCB Local Groups

from Jørgen Seldrup

National Groups

The Annual General in Budapest in August 1996 adopted a new constitution, as a result of which the creation and therefore existence of national groups became enshrined in the rules. The fact that The Society had both a Polish and a Hungarian national group, without the concept being recognised in the constitution, only goes to demonstrate, how overdue the new constitution was.

To formally (re)create the existing groups in the framework of the new constitution the Society is obliged to hold a postal ballot. Plans and preparations are now well advanced for holding such a ballot, but for practical reasons it will be tied in with the distribution of the Newsletter, not this one, but the May issue. In the meantime, we take comfort from the fact that no member of either the Polish or the Hungarian group will be disadvantaged due to the lack of "legal" status within the Society.

Jørgen Seldrup, Member of the Executive Committee

ISCB Aims



The Society is organized 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 harmonized standards of statistical practice;
- to work with other societies and organizations 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 organizations 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.

Advertising Rates



The new costs are:

Full A4 page: £ 200
Half A4 page: £ 150
Quarter A4 page: £ 100

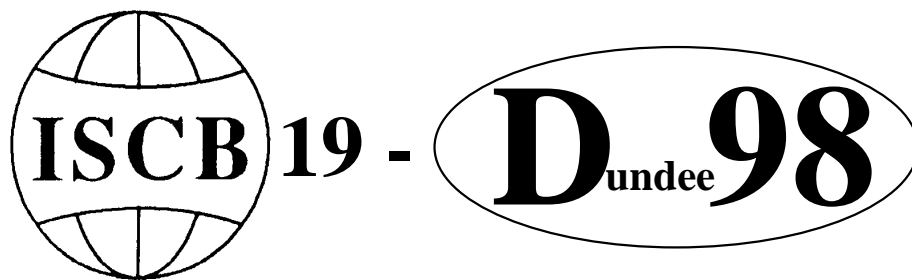
Additionally, we will include loose flyers with the distribution of the newsletter at an initial handling cost of £ 150. However, if the addition of the flyers increases the postal charges, the advertiser will also be charged the difference in distribution costs. For further information, please contact the Editor.

Publishing dates in 1997:

April, August and December

Deadlines:

end of March, July and November



Local Committee:

Dr Andrew Lawson, Mr Gilbert Rutherford (ABERTAY), Dr Giles Thomas, Dr Richard Brown (DUNDEE).

Scientific Committee:

Prof. Gillian Raab (NAPIER), Prof. Gordon Murray (EDINBURGH), Dr Jane Hutton (NEWCASTLE).

Sponsoring Universities:

Abertay Dundee, Dundee, Edinburgh, Napier, Glasgow, Newcastle

Venue:

Most likely will be The Stakis Hotel Dundee. This hotel is very central and has 1 x 400 seat room, which can split into 4 x 100 seat rooms, 1 x 70 seat room, and 3 x 30 seat rooms. Hence, we may be able to house all the conference in this locale if we split the large room for parallel sessions. There is a good low room rate package for people staying AND renting conference rooms here.

Hotels:

If the conference is held in the centre of Dundee then the following hotels can be used:

1) Stakis Dundee (4 star), 2) Discovery Inn (3 star), 3) Angus Thistle (3 star), 4) Invercarse (3 star), 5) Swallow Hotel (3 star). The total of rooms can be supplemented by student rooms in a new conference complex at West Park (Dundee Univ). Hotels 1,2,3 are in the

by Andrew Lawson

centre, while no 4) is on a good bus route into the centre. Hotel 5) may require a courtesy bus.

Reception:

There will be a reception on the first evening hosted by the City council

Conference dinner:

This can arranged at either: St Andrews Golf and Country Club or at the Letham Grange Hotel in Angus.

Trips:

A variety of trips are possible: Tour of City and Discovery Point, Tour of NE Fife: including St Andrews etc., Glens visit: walking or bus tour, Whisky tasting: Crieff or Pitlochry, Gleneagles visit, Dundee Heritage Trust, Tentsmuir forest walks

Organisation:

A local conference agency has now been set up in Dundee and it may be possible to get them to run the domestic arrangements.

One special feature of this meeting is that it's being planned early enough for us to issue the following:

"Call for Topics "

Yes, what would **you** like see as a topic at an ISCB meeting ?

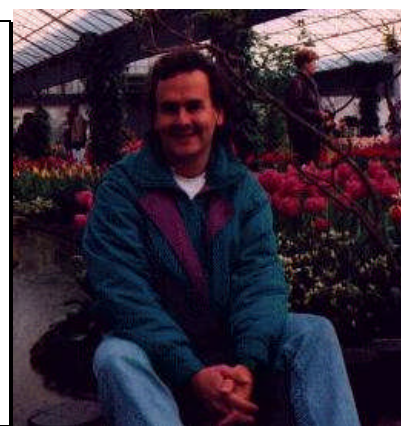
Please send your suggestions to me,
Andrew Lawson.

Getting a homepage started was relatively easy, but producing something more interesting using the latest extensions of the HTML language turned out to be much more difficult. CompuServe produces a Homepage Wizard and Microsoft has an Internet Assistant for Word, but neither produces anything too sophisticated, so I turned to a simple shareware product called QuickHTML. Also the choice of www browser is an important consideration (Netscape 3.01 or MS Internet Explorer 3.0 or good old Mosaic). But I hope you like the new appearance, full of colours, pictures and almost up-to-date information, as well as links to the Boston homepage, SCT, and all the members of the ISCB ExCom, and members of other subcommittees. Thanks again to KumWah Chang for some technical advice on fine-tuning the tables.

So what else is happening in the computer world ? I hear my former colleagues in Basel are upgrading to Word6, in good time for Microsoft's release of Word8 in January. Another version of SAS, 6.12, is due out soon just as I'm about to start using the newly installed previous 6.11 on a new Sun and new Novell network. That's progress - everything changing at the same time. C'est la vie !

If you've an event to announce, but the ISCB News publishing dates (April, August/September and December in 1997) aren't convenient, it will be possible to add something to mention your course or congress on the web homepage. Please contact the editor for details.

Articles sent via email or on diskette (Word6, WordPerfect 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.



by Nancy Geller

Probably the best way to learn about the World Wide Web is for someone to sit down with you and show you a trick or two. There is an amazing amount of information out on "the Web" and this outline is an attempt to be a surrogate for someone sitting down with you and showing you "the Web". It's based on a talk I gave to my Division after several alleged that the "Web" was "just junk". It is my hope that those who are more experienced "Web surfers" will gain a little, too. But, let's get on with it: those terms in quotations have to be explained.

1. Your new vocabulary

- www = World Wide Web, also known as "the Web".
- url = universal resource locator, read as either "u-r-l" or "earl". This means the web address.
- http = hypertext transfer protocol. This is how many urls begin. (Some begin with ftp:// or telnet:// or gopher://) If the address begins with http:// and you are using Netscape version or above, you don't have to type this part.
- html = hypertext markup language. This is a set of tags that make the pages look the way the creator wanted them to, irrespective of the computer and software you are using. html allows links to other web sites. The files themselves are ascii.
- Bookmarks = list of your favorite urls that you wish to access again.
- Surfing = looking around on the web. (Warning: time passes very quickly this way. You can hear your time going "WHOOOOSHSHS!" And if you are paying for your web connection, this can be a pretty expensive habit.)

2. Intelligent bookmarking

2.1 Setting Options. If you click on the "options" box and then on "General options", you can choose the web page which will come up when you first click on Netscape. You may choose your own web page or your institution's or company's.

2.2 Bookmarks. You can click on the "bookmarks" box to save ("bookmark") an interesting url to which you will want to return. I recommend that you bookmark only the top entry of a set of interesting ones, rather than each interesting one. An example is provided by the NIH url below, from which you can reach any of the National Institutes of Health (such as the National Cancer Institute) and from the National Cancer Institute, you can find information about various cancers on Cancernet. If you bookmark the NIH, you can search down easily, but it is not always easy to search up, say from Cancernet to another of the National Institutes of Health. Some of my bookmarks are found below.

3. Finding information

3.1. Search engines. Search engines index key words for all kinds of things. Different search engines result in overlapping, but not identical results. These are two search engines:

http://altavista.digital.com/	AltaVista (my favorite search engine)
http://yahoo.com	Yahoo (another search engine)

3.2. Guessing the url. Url's have a certain format and after you "surf" a while, you will begin to catch on. Here's an example. If I am seeking the e-mail address of someone at the University of Wisconsin, I try <http://www.wisconsin.edu> (because I know academic centers in the U.S. have ".edu" at the end of their address).

I get a message that Netscape is unable to locate the server; so I have to consider what would stand for "Wisconsin". I try <http://www.wisc.edu> and that works. I scroll down the page and see "directories" and that links with phone books and I am able to look up the person I seek. Needless to say, not everything is quite this easy, so I usually rely on the search engines to find url's.

4. Some urls of interest to biostatisticians

(It's very important to remember that parts of urls, at least the part beyond the first single slash, are case sensitive.)

http://www.ourworld.compuserve.com/homepages/David_W_Warne	ISCB home page
http://members.aol.com/sctbalt/index.htm	SCT home page
http://www.AMS.Med.Uni-Goettingen.DE/~rhilger/Biometry.htm	Reinhard Hilger's links to Biometry
http://www.biostat.washington.edu/Xvlib	Biostatistics
http://www.nih.gov/	National Institutes of Health
http://wwwicic.nci.nih.gov	Cancernet
http://www.nejm.org/	New England Journal of Medicine
http://www.magpage.com/~cwagner/	New Software

5. Some urls to try on your own

5.1. Some serious resources

http://xenia.sote.hu/e/email/ph-selserv.html	phonebook/email database server
http://www.bucknell.edu/~rbeard/diction.html	online dictionaries

5.2. For after hours fun

http://www.solutions.net/rec-travel/	Rec.travel library
http://www.city.net/	City info for travellers
http://home.earthlink.net/free/agh2o/webdocs/food.htm	Wonderful stuff about food and wine (exercise: find the Boston Zagat guide!)
http://www.intellicast.com/weather/intl/	world weather
http://www.msnbc.com/news/	Microsoft-NBC news (Best w. sound card)

So, if you've taken this outline seriously and followed the directions, several hours have already passed. As likely as not, you'll be back on the Web again very soon.

Surfing, anyone ?



As I waited at the desk of the customs officer at Budapest, late on a sultry August **Friday** evening, I was somewhat unexpectedly asked "Are you a bandit?". This subtle form of questioning no doubt leads to all smugglers owning up on the spot, but all I had was a couple of hundred Swiss Francs, soon converted to 10,000 Forints, enough to tide me over for the first few days. Little did I know how difficult it would be to spend it all in a week.

On **Saturday**, I dared to use the lift in the hotel despite the sign "Don't use in case of fire" (how subtle English word order can be), and after a hearty breakfast in a room full of Australians, South Africans and other English speakers touring Europe's capitals, it was off to explore the city. First a coach tour to get an overview of the sites, then lunch in a pleasant restaurant by the Danube... blue like the skies on one of the warmest days of summer. Having found the food to be wonderfully tasty and extremely cheap, my American colleague and I decided a boat trip would be an interesting way to finish the afternoon, and thanks to our German, we enjoyed the small tour of Margaret Island. Now I knew it was going to be a good week, as I won a book of photographs of Hungary in the boat's tombola.

Sunday was even hotter, approaching 34°, and the ExCom meeting was in the afternoon. Before then it was time to walk round on foot, to enjoy the magnificent sights of Buda and Pest. With the first metro in Europe after London, and an extensive network of 49 trams, a dozen of which run through the night, it was certainly easy to get around to see the many churches and monuments, many dating from Hungary's millennium exactly 100 years earlier. What a city of contrasts! Many Trabants that I'd only seen once before in Germany in '89, but also a fair number of expensive Mercedes and

Porsches. Many buildings falling apart, and poorly cobbled streets, not far from exclusive modern hotels and shopping precincts.

By now I was beginning to think spicy food wasn't such a good idea for a palette accustomed to milder Swiss recipes, and so the afternoon's committee work wasn't too much fun. But after several hours of discussion, it was time for a long-awaited event, the Welcome Reception. For the first time, this took the form of a musical hour of mediaeval music performed by "Vagantes". One comment I noted which summed up the feelings of us all was "what a wonderful way to start a conference!". Afterwards there was a magnificent choice of food again in the spicy Hungarian style.

Monday morning and a chance to practise my German with my former colleagues from Basel, and it was nice to find it hadn't been forgotten after a year of French. Getting to the opening talk for 9 am seemed a but beyond as us as we were still at the hotel at 8.50, but after piling into a taxi we arrived to hear Marc Buyse's welcome and the first plenary session on Philosophy, Past and Future of Clinical Biostatistics, and 3 talks by Gehan, van Houwelingen and Cox. In the following plenary on Graphical Methods in Clinical Research, there were talks on radial plots (Galbraith), the Trellis display (Cleveland) and Graphical displays for aggregate and disaggregate data (Wilkinson).

After finding the Platanus hotel and finding the food wasn't quite as good as the day before, it was back for the afternoon's proceedings. As in many conferences, the choice of which parallel session to attend was hard, but I opted for more on Graphical Methods, which contained an interesting and very colourful multi-dimensional presentation by Francis, and a fascinating "Representation of graphic data in anaesthesiological journals:

a proposed methodology for assessment of appropriateness" in which the appearances of various papers in terms of data density and data-ink ratio were compared.

The next session on Issues in Clinical Trials was followed by a quick journey back to the hotel and on to a wonderful Conference Dinner cruise along the Danube to admire the floodlit buildings of Buda and Pest. What a memorable evening, and a good opportunity to celebrate 2 years of leaving Basel.

Tuesday started with 2 invited sessions: talks by Simon, Schemper and Stare on Explained Variation in Statistical Models, and Disease Clustering and Geographical Analysis by Jacquez, Lawson and Richardson. In the session on Philosophy and Clinical Aspects, there were interesting papers by Hutton, Windeler and Högel. The day ended with an unusually lively and exciting AGM with the new constitution adopted unopposed, and an election with 9 nominees for 6 posts. Afterwards it was off to the city to try the famous Cafe New York and enjoy some more Hungarian food and gypsy music.

Wednesday started with a plenary session on Statistical Methods in Genetics, followed by a contributes session on Clinical Trials. After a poster session which gave a most interesting chance to talk to many of the authors, it was off on the Puszta tour, something I'd been looking forward to for many months. Horse riding is a famous tradition in Hungary and this afternoon and evening were unforgettable. It was becoming overcast as we left the capital heading southwards for a short stop in Szentendre for coffee and cakes. Eventually we arrived at the "ranch" and were invited to partake of the local schnapps, and a very bumpy carriage ride before the main horse show. The skills of the riders as they galloped round the arena either bareback or standing was breathtaking. There was a display of cracking 3m long whips and certain members of the audience joined in and won themselves

bottles of wine. After, a chance for me to get on one of the wonderfully trained horses for a quick canter round the menage, and the evening was rounded off by a meal in a typical country restaurant with Goulash being the main course. The photos of that evening will always remind me of just part of a great week. I went to bed tired and happy (partly not to have fallen off as riding can be dangerous)....

Thursday: I found that taking a shower can be even more hazardous than riding, and my back didn't appreciate the sudden contact with the floor of the bathroom. Undaunted and now familiar with the metro, I headed to the mini-symposium on Health Care Assessment and Pharmaco-Economics. As with recent conferences, this was the best session, with good talks from Varga, Urquhart, Harrell and Gore. The final session on Methods in Clinical Research brought the meeting to a close. And the day ended with a 3 hour committee meeting.

But there was still **Friday** to go, a tour to lake Balaton, the largest lake in Central Europe. Sadly it was a very misty cloudy day and not much could be seen. But the day was enjoyable nevertheless, as ISCB's contingent of Americans, Russians, Italians, Germans, and a Finn and a Brit enjoyed the day in what appeared from the signs everywhere to be a new German province. Thoughts turned from taking the curative waters to where to take the 2001 conference, e.g. Finland. Saturday morning dawned with heavy rain and back home after spending my last Forints on some beautiful Hungarian souvenirs.

To sum up, I can't imagine a more enjoyable, well-organised conference. Thanks to Bela Hajtman and his small team for their magnificent efforts over many months, overcoming many difficulties, often at the last minute. Thank you and congratulations !

ISCB History

O=Organiser, CH=Chairman, P=President, VP=Vice-President, S=Secretary, T=Treasurer, E=ExCom, NL=News Editor, N=NomCom

Date	NL (#p)	ISCB	Note	Wilson	Dixon	Van Strik	Marubini	Sancho-G'r	Jesdinsky	Seldrup	Gehan	Köpcke	Gallus	Lorstad	Does	Chastang	Armitage
1978		0 Brussels (B)															
May79		1 Brussels (B)	(1)														
Sep80		2 Exeter (UK)	(2,3)	T	S												
Sep82		3 Rotterdam (NL)				O	P										
Sep83		4 Paris (F)				P		O									
Sep84		5 San Marino (I)		VP	S	PP	O		P	E	E	T	E				
Jul85	1 (4)									NL							
Sep85		6 Düsseldorf (D/GMDS)		P	S	E		VP	PP O	E	E	T	E				
Jan86	2 (6)									NL							
Jul86	3 (4)									NL							
Sep86		7 Cardiff (UK)		PP O	E	E		P		S	VP	T		E			
May87	4 (6)			NL													
Sep87		8 Goteborg (S)		E	E	E		PP		S	P	T		VP O			
Aug88		9 Innsbruck (A)	(4,5)	T	E	E	E			S	PP	VP		P	E	E	
Oct88	5 (6)			NL													
May89	6 (8)			NL													
Sep89		10 Maastricht (NL)	(5,6)	T	E	E	E			S	E	P		PP	EO	E	VP
Nov89	7 (8)													NL			
May90	8 (8)													NL			
Sep90		11 Nimes (F)	(6,7,8)	T						E	E	PP	E	S		VP O	P
Nov90	9 (8)									NL							
May91	10 (12)									NL							
Jul91		12 Brussels (B/SCT)	(8,9)	T						VP	E1 N2	E1	E	S		P	PP
Nov91	11 (12)									NL							
May92	12 (12)									NL							
Aug92		13 Copenhagen (DK)				N1				P1	E2 N3	E2				PP1	
Dec92	13 (12)																
Jun93	14 (20)																
Sep93		14 Cambridge (UK)	(10)			N2				P2						PP2	
Dec93	15 (32)																
Jun94	16 (32)																
Jul94		15 Basel (CH)	(10,11)			N3				PP1							
Dec94	17 (32)																
Jun95	18 (24)																
Jul95		16 Barcelona (E)	(12)							PP2							
Dec95	19 (32)																
Jun96	20 (32)																
Aug96		17 Budapest (H)	(12)							E1							
Dec96	21 (28)																
Apr97	22																
Jul97		18 Boston (USA/SCT)								E2							
Aug97	23																
Dec97	24																
Jun98	25																
Aug98		19 Dundee (UK)	(13)														
Dec98	26																
Jun99	27																
Aug99		20 Heidelberg (D/GMDS)															
Dec99	28																
Jun2000	29																
Aug2000		21 Trento (I)															
Dec2000	30																

Notes:

(1) Staquet=O, (2) Harris=O&Chair, (3) Read=E, (4) Neiss=E&O, (5) Morabito=E, (6) Zwingers=E, (7) Daures=E, (8) Heyting=E, Krusinska=E

ISCB History (2)

O=Organiser, P=President, VP=Vice-President, S=Secretary, T=Treasurer, E=ExCom, NL=News Editor, N=NomCom

Buyse	Schmidt	Senn	Evans	Day	Huitfeldt	Johnson	Valsecchi	Van Houw'n	Warne	Geller	Hajtman	Schemper	Cobos	Campbell	Cesana	Colton	Whitehead	Date	
																			May79
																			Sep80
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E O	E	E	N1																Jul91
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																			May92
VP1	T1 O	S1	N2	E1	E1	E1	E1	E1											Aug92
									NL										Dec92
									NL										Jun93
VP2	T2	S2	N3	E2 O	E2	E2	E2 N1	E2	NL	E1									Sep93
									NL										Dec93
									NL										Jun94
P1	VP1	S1		E1	T1	E1	E1 N2	E1	NL	E2	E1	N1							Jul94
									NL										Dec94
									NL	E1									Jun95
P2	VP2	S2		E2	T2	E2	E2 N3	E2	NL		E2	N2	E1 O						Jul95
									NL										Dec95
									NL										Jun96
PP1	P1			S1	T1				NL	VP1	O	N3 E1	E2	E1	E1	E1	E1		Aug96
									NL										Dec96
									NL										Apr97
PP2	P2			S2	T2				NL	VP2 O		E2		E2	E2	E2	E2		Jul97
									NL										Aug97
									NL										Dec97
									NL										Jun98
	PP								NL	P1									Aug98
									NL										Dec98
									NL										Jun99
									NL	P2									Aug99
									NL										Dec99
									NL										Jun2000
									NL	VP									Aug2000
									NL										Dec2000

(9) Bassein=N, (10) Guggenmoos-Holzmann=E, (11) Schenker=O, (12) Altman=N, (13) Lawson=O

*from Chairman: Prof. Dr H. Schäfer, Institute of Medical Biometry,
Bunsenstr. 3, D-35037 Marburg, Germany, email: haegar@pcisn03.med.uni-marburg.de*

At ISCB in Budapest, the committee decided to constitute a Subcommittee on Statistics in Regulatory Affairs. The members of this subcommittee are Prof. Helmut Schäfer (chairman), Prof. Stephen Senn, Dr Karsten Schmidt, and Dr Jørgen Selstrup.

The main task of this subcommittee will be to review draft guidelines and draft directives on drug regulation at the European and international levels, and to prepare coordinated comments on these. This had previously been stated as a task of the SEDREG group, but was sorted out from the task list of SEDREG on the meeting on 22nd January 1993. Thanks to the activities of SEDREG, the ISCB had received a mandate from numerous national biostatistical societies in the European member states. The European Commission only accepts contributions from European societies, not from national societies.

The chairman of the Subcommittee on Statistics in Regulatory Affairs had contacted the European Commission in May 1995 (personal visit to Dr Deboyser) and the EMEA (letter to Prof. Bass) and offered the services of the ISCB in the preparation process of European drug regulations. As a result, the EMEA has put the ISCB on the mailing list for drafts distributed to 'interested parties' in order that the subcommittee "would be in a position to comment for ISCB on drafts distributed to 'interested parties'" (quotation from the letter by Prof. Bass, EMEA, to the chairman of the subcommittee).

In May 1996, the subcommittee received a draft directive "on the approximation of provisions laid down by law, regulation or administrative action relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use". The comment of the ISCB subcommittee to this draft proposal, signed by the President of the ISCB, was sent to the European Commission with a letter dated 27th August 1996. In this comment, three proposals were made:

1. The directive should emphasise the importance of statistical principles and methods by referring to the recently published CPMP Note for Guidance on Biostatistical Methodology in Clinical Trials. In the draft of the directive, no such referral was made.
2. The ISCB welcomed the proposal of an approval procedure for clinical trials by the competent authorities, but proposed specifying explicitly the most important criteria of approval (the objective and the design of the trial, the quality and manufacture of the investigational medicinal products, the toxicological and pharmacological tests, the clinical information on the investigational medicinal product.)
3. The ethics committees should consider the validity of the trial design in preparing its opinion.

The subcommittee has not received reactions to these comments yet.

Preparing and coordinating comments on draft guidelines and draft directives will be a task of increasing importance, and the subcommittee will continue this work. The next step must be to renew and to define exactly the mandate of national biostatistical societies and to intensify the contact to the European Commission and EMEA Societies interested in this cooperation should contact the chairman of the subcommittee.

by Nancy Geller, on behalf of the ISCB ExCom

The International Society for Clinical Biostatistics (ISCB) is pleased to extend its warmest congratulations to Professor Roel van Strik on the occasion of his 70th birthday:

The ISCB held its first meeting in May of 1979 in Brussels and Professor van Strik was present. It is thought that he was skeptical about forming ISCB, believing that the regional groups of the International Biometric Society could serve the intended purpose. He soon realized that ISCB could unite clinical biostatisticians in Europe in a way that regional groups of the Biometrics Society, with their diverse interests and national affiliations, could not.

He began to play an active role in ISCB activities soon after the Society was formed. He organized the September 1982 annual scientific meeting, which was held in Rotterdam and then became president of the Society in 1983-84. Following a year's tenure as president and another as past-president, he continued to serve the ISCB for five years as a member of the Executive Committee. More recently, Professor van Strik served as a member of the Nominating Committee for three years during the 1990's and was the first chair of the first Working Party established by ISCB on Statistics in European Drug Regulation (SEDREG). The early theme of SEDREG was to press for the employment of statisticians in the regulatory process and Professor van Strik was instrumental in contacting a long list of national statistical societies, seeking and obtaining their support for the ISCB initiative of demonstrating to regulatory bodies the important role of statisticians in the evaluation of drugs.

In his quiet and low key way, Professor van Strik has been able to encourage others in the Society to undertake a great variety of activities. Although always modest, he has confessed that he has attended every single ISCB meeting. Aside from the many elected offices he has held in the Society, he has served on the Program Committee for the annual meeting several times, has chaired many sessions over the years and has himself presented a number of papers. It is hard to think of any job, large or small, he has not done in ISCB.

Aside from his active participation in ISCB formal activities, Roel is known as an all-around cheerful fellow who likes to have a good time. He was known to enjoy the folk dancing at the ISCB-14 annual banquet in Cambridge and one ExCom member recalls an evening at ISCB-11 in Nimes when several ended up in Roel's hotel room to share some Genever (a Dutch brandy). To the surprise of some attendees, the drink was rather potent. It is hard to assess the long-term effect of that evening on the history of ISCB, but, we are told, good fellowship has greatly increased.

We shall always picture Professor van Strik at an annual ISCB meeting wearing his meeting briefcase cross chest, so as not to lose it. He is ever smiling and looking fit and always has a kind word and good story to share. It is hard to believe he is turning 70! Indeed, his vigour is an inspiration to those of us who follow.

The ISCB officers and Executive Committee express their appreciation to Roel van Strik for his guidance and many contributions to the ISCB and hope its growth and development reflect his vision.



Story from Budapest

by Jørgen Selstrup

Did this happen at the Hotel Platanus in Budapest ? The following is adapted freely after Dr Nancy Geller, who recounted to me an actual story of an incident between a London hotel and one of its guests. The Hotel ended up submitting the letters to the London Sunday Times !

Dear Restaurant Manager,

Having arrived only yesterday, Sunday, late, your restaurant was unable to provide any food, so it was with some relish I awaited breakfast room service this morning, only to be rather disappointed by your buns, the abundance of which rather belies ones ability to cut, break or otherwise force them open in order to supply the necessary butter to ease the passage and digestion of the baked material. I would appreciate the opportunity to have toast for breakfast tomorrow morning. Thank you,

Ian S C Bolle

Dear Room 32,

I am your deputy restaurant manager. The regular manager will be back tomorrow, Tuesday. I have no authority to provide our guests with toast. Instead, I have supplied an extra bun and one tub of marmalade. I would appreciate your keeping any left over marmalade for your breakfast on Tuesday. I hope this is satisfactory.

Janos, Deputy Restaurant Manager.

Dear Restaurant Manager - I hope you are not his deputy.

Apparently Janos, your deputy, did not tell you about my note to him concerning your rather tough breakfast buns.

When I got back from my shower this morning, I found your room service had once more given me two of your breakfast buns, which, judging from ones inability to get into them without crumbing everywhere, let alone chew and swallow them, must now be at least three days old. I really would appreciate the opportunity to have toast for breakfast tomorrow morning.

Ian S C Bolle, Room 32

Dear Mr Bolle,

The Restaurant Manager informed me this morning, that you called him and said you were unhappy with our breakfast menu. I would like to invite you to attend the restaurant, where the Restaurant Manager will be personally able to attend to your wishes. I hope, you will accept my apologies for any past inconveniences. If you have any future complaints, please contact me, so I can give it my personal attention. Call extension 1108 between 10 am and 4 pm. Thank you.

O Kovazyi, Hotel Manager

Dear Mr Kovazyi,

It is impossible to contact you by phone, since I leave the hotel for the ISCB Conference at 8:45 am and don't get back until after 6 pm. That's the reason I called your Restaurant Manager. You were already off duty. I only asked The Restaurant Manager to please let me have toast in the morning, rather than any number of your indigestible buns. Why can't I have a simple toast with butter and marmalade. Do you not have a toaster in your hotel ? Incidentally, I am going to stay here for another four days and I am running out of soap; clean towels would also be most welcome. My bedding is yet to be changed.

Ian S C Bolle

Dear Mr Bolle,

Our Restaurant Manager has been instructed to stop delivering breakfast buns to your room and provide you with toast in the restaurant. If I can be of further assistance, please call extension 1108 between 10 am and 4 pm. Thank you,

O Kovazyi, Hotel Manager

Dear Restaurant Manager,

I came down for breakfast this morning at 8 o'clock and sat at table 7. Having waited for what I considered long enough to have my table cleared, I was 'invited' to go and sit at an other table, only to be told on ordering toast and marmalade, that there was no more toast, but plenty of breakfast buns - as many as I wanted.

Ian S C Bolle

Dear Mr Bolle,

I have informed our Restaurant Manager of your wish to have toast in the morning. I cannot understand, why there was no toast left, since the waiters are instructed only to serve toast on special request supported by my authorisation. The situation will be rectified immediately. Please accept my apologies for the inconvenience.

O Kovazyi, Hotel Manager

Dear Restaurant Manager,

Who the hell decided not to bring me my breakfast this morning? Last night I ordered breakfast in my room at the usual time of 8 am. As nothing was brought, I took my usual shower. Mind you, the piece of soap is now so small, that should I drop it on the floor, it will be gone forever. I look forward to leaving tomorrow.

Ian S C Bolle

Dear Mr Bolle,

You complained about our standard breakfast buns, so you were invited to have toast, as you had requested, in the restaurant. Then you complained, that we had run out of toast, so quite frankly, when you did not show up this morning I decided, that you clearly dislike everything we have on offer in our restaurant, thus no breakfast was delivered this morning.

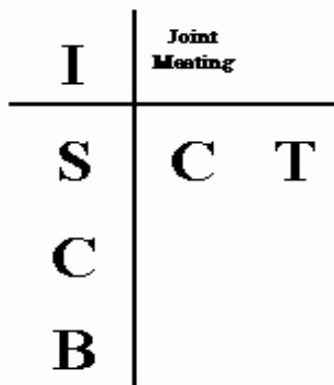
The Restaurant Manager

Dear Mr Kovazyi,

Just a short note to say what a wonderful week I have had in your beautiful city and to bring you up-to-date on my final experiences at your hotel. I did stay the full length of my booking and I was so glad I did. The last morning, Sunday, I decided to go down to the restaurant for breakfast. And what a pleasant surprise. Not only could I have toast, I could have the loveliest buns, I have had for a long time. The table I decided to sit at was swiftly cleared and I was invited to enjoy your hotel's renowned breakfast. Incidentally, I had a really bubbly shower this morning, thanks to the new bar of soap; and what a pleasure to be able to dry yourself without having to try to remember which corner of the towel was last on the floor; I slept heavenly in fresh clean linen. I only felt sorry for the second taxi driver, who had come to take me to the airport. He insisted he had been booked by The Porter.

Ian S C Bolle





As has been announced previously, ISCB will meet jointly with the Society of Clinical Trials (SCT) at the Marriott Hotel at Copley Square in Boston, Massachusetts, U.S.A. from July 6-10, 1997. This is an update on the planning for that meeting.

The planners are very excited about the home page which SCT was kind enough to put up on the World Wide Web. On the SCT home page (<http://members.aol.com/sctbalt/>) you will find links to Boston information as well as a downloadable abstract form and instructions for submission. And now ISCB and SCT have links to each others' Home pages.

By the way, the new, updated ISCB home page is beautiful and informative ! See http://ourworld.compuserve.com/homepages/David_w_warne/.

The abstract deadline for contributed papers is 15 January 1997. There is also a Student Scholarship contest and information about that appears in a separate article in this newsletter.

There have been a few changes in the invited sessions. The preliminary titles of invited sessions are given below and final confirmation from invited speakers is now being obtained. The mini-symposium is planned for the afternoon of July 10th.

Plenary sessions:

1. Errors in clinical trials: ethical and methodological perspectives
2. Synthesising the world's reliable evidence on health care: statistical methods in the Cochrane Collaboration
3. The impact of external events in ongoing clinical trials
4. "Controlled Clinical Trials" and "Statistics in Medicine" salute Nathan Mantel

Mini-symposium:

Analysis of noncompliance in clinical trials

from Nancy Geller

Workshops

1. Vaccine clinical trials
2. Developing effective statistical leadership in clinical research
3. Initiatives from the international conference on harmonization of technical requirements for the registration of pharmaceuticals for human use (ICH)
4. Mid-course modifications in clinical trials
5. Multiple endpoints in clinical trials
6. Preparation and review of the integrated summary of safety (ISS) for a new drug application (NDA)
7. Prospective meta-analyses of clinical trials
8. Survival analysis
9. Analysis of longitudinal data
10. Surrogate markers
11. Missing outcome data

Progress, too, has been made on the social events. The banquet will be held at the New England Aquarium on Monday night located on Central Wharf. It will be very informal and feature a New England Clambake. "Very informal" means that service will be buffet style on paper plates, but there will be a full dinner served, including a lobster. The cost is anticipated to be \$60-65 with reduced rates available for children. We will be able to wander through the main exhibition during the evening after the Aquarium is closed to the public. An exciting and uniquely American evening is anticipated.

We hope to see you in Boston. Further information about the joint 1997 ISCB/SCT meeting may be received from Mary Burke, Joint Meeting ISCB/SCT, 600 Wyndhurst Ave., Suite 112, Baltimore, MD 21210 U.S.A., telephone +1 410 433-4722, fax +1 410 435-8631, e-mail: sctbalt@aol.com. Nancy Geller, the chair of the ISCB local arrangements committee, may be reached by e-mail at ng@helix.nih.gov.

COME TO BOSTON FOR THE JOINT SCT/ISCB MEETING IN 1997 !

1997 Conference: Student Scholarship Program

from Rick Chappell

STUDENT SCHOLARSHIP PROGRAM: SOCIETY FOR CLINICAL TRIALS / INTERNATIONAL SOCIETY FOR CLINICAL BIostatISTICS JOINT MEETING, JULY 6 - 10, 1997, BOSTON, MA, USA

The 1997 Joint Meeting of the Society for Clinical Trials (SCT) and the International Society for Clinical Biostatistics (ISCB) will sponsor a Student Scholarship Program. This program has been traditionally sponsored by SCT to stimulate student involvement in the Society. Students are invited to submit abstracts, along with a short manuscript (not to exceed three pages).

ELIGIBILITY

All students enrolled in a degree program of an accredited college or university, post-doctoral fellows, or physicians enrolled in an accredited residency program. The manuscript must relate to original work that has not yet been published. Student eligibility will be assessed at the time of submission.

TOPIC

The presentation must concern clinical trial-related issues. Sample topics include (but are not limited to) Design or analysis of a specific trial or class of trials, Review of results or methods of a class of trials, Medical, legal or ethical issues related to clinical trials, Data entry, management, and computing as applied to clinical trials.

SUBMISSION PROCEDURE

Manuscripts should be no more than three double-spaced pages. Abstracts should be submitted on an official abstract form. Seven copies of both abstract and manuscript should be submitted. A letter from the student's faculty advisor stating that he/she is a bona fide student and briefly describing the student's course of study should accompany the submission. If the manuscript is co-authored, this letter should also include an indication of the level of involvement of the various authors. The deadline for submissions is JANUARY 15, 1997.

REVIEW AND PRESENTATION

Selections are made by the Student Scholarship Committee which contains representation from both societies. Four students are expected to be named as presenters; winners will be notified by March 1. By May 15, 1997, they are required to provide Scholarship Committee members with a copy of the complete paper they will present. A session at the Joint Meeting will be set aside for Student Scholarship paper presentations and discussion.

AWARDS


Those selected to present papers will be invited to the meeting with all fees waived and travel and living expenses paid, subject to a negotiable \$1750 US limit. The student judged to have the best paper will receive the Thomas C. Chalmers Student Scholarship prize and a \$500 cash award.

OBTAIN ABSTRACT FORMS/ MAIL MANUSCRIPTS:	FURTHER INFORMATION:
Secretariat Society for Clinical Trials, Inc. 600 Wyndhurst Avenue Baltimore, Maryland 21210 USA	Rick Chappell, Ph.D. University of Wisconsin - Madison Department of Biostatistics 600 Highland Ave., K6/430 Madison, WI 53792 USA
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Books and Software for Review

Books

(1) The following books are available for review. Please contact the editor if you would like one or more of them. Reviewers are allowed to keep the book(s) that they reviewed (3.5" disks or email preferred, deadline for reviews: 3 months after receipt).

 Yandell BS	Chapman & Hall (1997)	<i>Practical data analysis for designed experiments</i>
Kocherlakota S & C	Marcel Dekker (1992)	<i>Bivariate discrete distributions</i>
Lutz EW (ed.)	Marcel Dekker (1991)	<i>Future demographic trends in Europe and North America: What can we assume today ?</i>

(2) Reviews awaited (*due to logistical delays, and no fault of the reviewers):

Julia Singer	*Maxwell & Delaney (Wadsworth)	Designing experiments and analyzing data: A model comparison perspective
	*Ott & Mendenhall (PWS-Kent)	Understanding Statistics
	Hutchinson TP (Rumsby)	Essentials of Statistical Methods. Version 4, Health and Sickness series.
Anna Bartkowiak	Cox DR & Wermuth N (Chapman & Hall)	Multivariate Dependencies: Models, analysis and interpretation.
Aurelio Tobias	*Scheaffer (PWS-Kent)	Introduction to probability and its applications
	Armitage P & Berry G (Blackwell)	Statistical Methods in Medical Research. 3rd edition.
Weichung Joe Shih	Carstensen JT (Marcel Dekker)	Drug stability - Principles and practices. 2nd edition.

(3) Reviews long awaited:

David Owens	Guarino (Marcel Dekker)	New drug approval process
	Singer & Upton (Marcel Dekker)	Guidelines for laboratory quality auditing

(If anyone knows this person, please ask him to pass on the books to someone who will review them !)

Software

(4) Reviews long awaited:

Stephan Evans	N, Nsurv, TESTIMATE	IDV, Gauting
Joan Houghton	Random	Wiedey
	Rancode	IDV

(If anyone knows these people, please ask them to pass on the software to someone who will review them !)

Publishers: I would be very grateful if you would send some new books to the Society's Permanent Office !



How to Contact the ISCB Executive Committee (ExCom)

	Address	Tel:	Fax:	Email:
ISCB Permanent Office:	ISCB, PO Box 25, DK-3480 Fredensborg, Denmark	+45 48 484100	+45 48 484200	lscb@post3.tele.dk
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<i>Secretary:</i> Mr. Simon J. Day (UK)	LEO Pharmaceuticals, Longwick Road, Princes Risborough, Bucks. HP27 9RR, UK	+44 1844 347333	+44 1844 346088	---
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Prof. John Whitehead (UK)	MPS Research Unit, The University of Reading, PO Box 240, Earley Gate, Reading RG6 6FN, England-UK	+44 118 9318027	+44 118 9753169	j.r.whitehead@reading.ac.uk

ISCB News: News !

ISCB Changes of Address

Please inform the Vice-President who looks after money and also the membership and mailing list databases.

ISCB: The Future

Boston, USA, 1997 and Dundee, Scotland-UK, 1998: please note announcement in this News. Further details to follow in 1997 and 1998 on



2001+: Proposals for conferences for these years are continuing to take shape, with various ideas, including Finland, under consideration. If you have ideas about organising a future conference, the ExCom would be happy to receive them. Meetings in countries that have not hosted ISCB before would be particularly welcome.

ISCB ExCom

There were 2 meetings of the ExCom in Budapest, interspersed with the AGM at which new members were selected. The following is a brief summary of the discussions and decisions:

ExCom1:

The following topics were reviewed and discussed: Proposal for a meeting in Trento, Italy; Matters arising from ISCB16 Barcelona; Budapest Meeting; the AGM; the new Constitution; ISCB18 Boston; Other meetings. Presentations including Dundee and Heidelberg; Reimbursement Policy for expenses; Advertising with the Newsletter; SEDREG; new Regulatory subcommittee;

ExCom2:

Review of Budapest meeting (a Great Success !); Future meetings; Communications within ExCom; Homepage and email; Student scholarships; Fraud subcommittee; SEDREG subcommittee; Statistics in Regulatory Affairs subcommittee; Education subcommittee; Nominations and Ballot subcommittees; National Groups; Newsletter; ISI Affiliation; Auditors; Journal of Epidemiology and Biostatistics.

Curtis L Meinert: Clinical Trials Dictionary, Terminology and Usage Recommendations

The Johns Hopkins Center for Clinical Trials, Baltimore.
\$95 (+\$25 airmail delivery outside US).

This is truly a dictionary ("book explaining the words of a language or words and topics of some special subject"). There is emphasis on explanation, over and above mere definition (look those two words up in a conventional dictionary and get precise *definitions* and then I should not need to *explain* my point further). But before getting onto the word/phrase listing, let me describe some of the surrounding features.

The book opens with four pages of explanatory notes where the style, layout, means of cross-referencing, etc. are explained. It is crucial to understand that the book is intended to be comprehensive so that, for example, the entry *randomized controlled clinical trial* refers the reader to separate entries under *randomized*, *controlled*, *clinical* and (yes, you guessed) *trial*. Such comprehensiveness (although an advantage) enormously increases the volume of the work (a disadvantage). My opinion is that some of the extent of cross-referencing is unnecessary but given the scope of what Dr Meinert has stated he has set out to do, that is how this reviewer will judge the result. Besides, if terms are cross-referenced, you are not obliged to look them up; rather the opportunity is there should you wish to. No-one can complain about that !

Twenty-three pages cover "Usage practices, cautions and recommendations". This is not the kind of material I would expect to see in a dictionary but it is very valuable. It obviously draws on the author's enormous experience of writing, reading and editing. He gives some wonderful examples (mostly not from scientific literature although I'm sure he could have found some howlers if he had tried) of not saying what is intended: "May I help you" should actually be interpreted as "What do you want ?" "Do you have an ID card ?" actually means "Who are you ?" Words such as "applied" can be offensive, can't they? Think about it... Someone who claims to work in "applied research" may essentially be criticising those who sit in their ivory towers doing "theoretical research". Maybe no criticism is intended but care with language is all important. Reading these pages educated me and embarrassed me. I'll write more carefully in future. (Dr Meinert would criticise that last sentence but I'll leave you to figure out why !) The underlying message from this section of the book is that clear language in scientific writing is essential. My personal gripe on this subject is the confusion caused by ambiguous references to "mean differences" and "differences between means"; and if you do a *t*-test based on data that are changes from baseline to endpoint, do you properly describe the estimate as being the "difference between mean differences" or something else ? (I refer you to Appleton D R, "Cross words" *Brit*

Med J 1994;309:1737-8 for further insight on such ambiguities.) And one final request, do we "randomise patients to treatments" or "randomise treatments to patients" or doesn't it make any difference ? Enough of my ramblings...

There is a Glossary of Terms and then 58 pages of Listing of Entries with the relevant page number. Since the substance of the Dictionary is naturally in alphabetical order, this listing seems a little redundant. A minor point. Then come over 4300 terms and 6400 definitions (so the cover says, I didn't check) covering 300 pages and encompassing the languages of medicine, biostatistics, epidemiology, computer science and bioethics. There are 171 references and then a 49 page index (again, maybe a little unnecessary).

So to the main part of the dictionary...

What do I think of it ? Very American in style and content ! Not that there is necessarily anything wrong with that but, for example, *FDA* is listed but *CPMP* isn't; the *Society of Clinical Trials* (oops, it should be "Society for Clinical Trials") is listed but a certain predominately European based society with interests covering many of those of SCT (you're reading its newsletter) is not. There is some European content: *Hill, Sir Austin Bradford* is listed - a fine British gentleman and therefore a true European, if ever there was (or ever will be) one !

Nuremberg is listed as "City in the SE portion of Germany; site of World War II war crimes trials". *Nuremberg Code* is listed and its leading to the *Declaration of Helsinki* (listed) but the need for *Nuremberg* as a stand alone term seems excessive. A slight editorial slip, perhaps, here: *Nuremberg Code* actually refers the reader to *Helsinki Declaration*; look up *Helsinki Declaration* and you get nothing except a reference to *World Medical Association Declaration of Helsinki*; look that up and (amongst other things) you get a reference to *Declaration of Helsinki* which contains nothing except a reference back to *World Medical Association Declaration of Helsinki*. It all seems to be a bit of a run around the houses.

In general, the US spellings and content I can live with, but the usage notes present more of a problem to me. I'll give a *haphazard* (listed) selection of comments but I am mindful of the fact that "criticism is easier than craftsmanship" (I'll return to that comment later).

Blinding is one of my current interests and I was disappointed to see the usage note say that it was not recommended but *masking* should be used instead. I agree there are instances where *masking* may be a better term but I would not like to go so far as to say the term *blinding* is not recommended.

Throwaway medical journal is an example of the broad coverage of this work. Is such a term really necessary? (Note, I hope you do not think you are reading a throwaway statistical journal !)

Bias is listed along with *biased coin randomization* and *biased coin treatment assignment*. But does *coin* need to be listed? (It is defined as "A flat, thin, and usually round, metal object having opposing and differing faces".)

Some of the statistical terms are a nightmare to explain (definitions are much easier than explanations). He does well with *null hypothesis* although to get a full explanation you also have to go and look up *statistics*, *hypothesis*, *populations*, *factor*, *trait*, *characteristic* or *condition*. And when you get to any of those points, there are more leads to follow.

Confidence interval is well tackled but in reading such highly technical sections it becomes clear that the audience most likely to benefit from the dictionary are those people with a basic science background and not, for example, secretaries and other more administrative support staff (you know the sorts of people I mean: the ones without whom, the whole process would grind to a halt !). This makes one wonder who the Dictionary is aimed at. It is clearly impossible to aim at too broad an audience without including material that will be unnecessary for many groups of readers. Some compromise is always necessary.

A few terms are usefully explained by diagrams, examples are *frequency polygon*, *Poisson distribution* and *Venn diagram*. Similarly, some terms contain mathematical details or formulae, examples are *Bayes' theorem*, *inverse sine transformation* and *permuted block*. Perhaps *two-by-two table* or *contingency table* might have benefitted by small illustrative tables.



There is no way I intend to trawl the 300 pages and find which terms should be there but have been missed. That would be unfair. Besides, identifying terms that should be there but aren't, or identifying terms that are not there but should be merely represents a statement of my opinion. As a single sweeping statement I have to say that the judgement of coverage is mostly very good. Most of the terms I have at least a basic understanding of but I expect to use this book frequently to get a further opinion.

As I said earlier, and promised to return to, "criticism is easier than craftsmanship". The work is liberally scattered with little quotations. Each section beginning a new letter of the alphabet is initiated with one. Some of these are highly perceptive, some flippant, some just weird ! [We'll put them in the next edition of the *ISCB News* - ed.] All this helps to make the book a great read. I highly recommend it as a very valuable source of reference and as a fascinating tour that will take you from *a-*, *an-* ("prefix - Without, not, as in asexual") to *zeta* ("n - [Gk zeta] The 6th letter of the *Greek alphabet*, uppercase Z, lowercase ζ").

Samuel Johnson said "Making dictionaries is dull work". I say "Reviewing them is much more fun". I got the easy job but unlike Johnson, I don't suppose I'll be quoted in 300 years time !

Advert: George Washington University

**Assistant to Full Professor of Statistics and Biostatistics
The George Washington University**

The Department of Statistics and its research facility, the Biostatistics Center, are conducting an open-rank recruitment (Assistant to Full Professor) with tenure or tenure accruing, for a position starting in the summer/fall of 1997. The position is funded full time on a 12-month basis. It will entail academic responsibilities in the Department of Statistics and methodological support of the medical research activities at the Biostatistics Center.

The Department, the Biostatistics Center, and the proposed School of Public Health and Health Services (to be established in July 1997), jointly offer advanced degrees in biostatistics and epidemiology. The Department also offers masters and doctoral degrees in statistics. The Biostatistics Center serves as the Coordinating Center for large scale cooperative clinical trials and epidemiologic studies. A unit of the Biostatistics Center also supports research activities within The George Washington University Medical Center.

Responsibilities include: teaching 2-3 courses per year, supervision of doctoral students in support of the Ph.D. programs in biostatistics and statistics, serving as a methodological statistical collaborator for Biostatistics Center research projects and conducting original methodological research to meet the statistical requirements of ongoing medical research projects. A record of research in statistical methods directly related to clinical trials and epidemiologic studies is required.

Applicants for senior rank positions will be judged on the quality and relevance of their past research and their teaching capabilities. Applicants at the Assistant Professor level will be judged on the quality of their training and the promise of their early research for future impact in biostatistical practice. A minimum of two years postdoctoral experience is required. Salary will be commensurate with experience and past performance. It is anticipated that funding will be available July 1, 1997.

Review of applications will begin January 1, 1997, and will continue until the position is filled. Please send resume and three letters of reference to: Dr. John M. Lachin, Professor of Statistics and Director, The Biostatistics Center, 6110 Executive Boulevard, Suite 750, Rockville, Maryland 20852.
[HTTP://WWW.BSC.GWU.EDU](http://WWW.BSC.GWU.EDU)

The George Washington University is an Equal Opportunity/Affirmative Action Employer.

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 pharmacoepidemiology. Each meeting includes a mini-symposium devoted to a particular medical or statistical field. Recent examples have been Organ Transplantation, Regulatory Affairs in Europe and North America, Quality of Life, Statistics in Medical Journals, Prevention Trials, Innovative Methods in Drug Development, Vaccine Trials, and Healthcare Assessment and Pharmaco-Economics.

Previous meetings in recent years have been held in Cardiff (1986), Gothenburg (1987), Innsbruck (1988), Maastricht (1989), Nimes (1990), Brussels (1991), Copenhagen (1992), Cambridge (1993), Basel (1994), Barcelona (1995) and recently in Budapest (1996).

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 of £150.

The ISCB also organises courses to cover particular statistical topics. These are run to precede or follow on from the annual scientific meeting and are given by the foremost researchers in the field. Recent courses have included Non Parametric Methods in Medical Research, Decision Analysis in Early Phase Drug Trials, Analysis of Longitudinal Data, Martingales in Survival Analysis, Issues in the Design of Clinical Trials, Sample Size Calculations in Clinical Trials, Overdispersion, Repeated Measures and Longitudinal Data, Analysis of Ordered Categorical Data, Cross-over Trials in Clinical Research, Analysis of Repeated Measures, Survival Analysis, Extending the Cox Model, and Statistical Methods for Genetic Epidemiology.



The current composition of the **Executive Committee (ExCom)** is as follows: **Officers:** President, Dr Karsten Schmidt (Denmark), Vice-President, Dr Nancy Geller (USA), Secretary, Mr Simon Day (UK), Treasurer, Dr Bernhard Huitfeldt

(Sweden), and **Members:** Newsletter Editor, Dr David Warne (Switzerland), Past President, Dr Marc Buyse (Belgium), and Dr Mike Campbell (UK), Dr Bruno Cesana (I), Dr Albert Cobos (Spain), Prof. Ted Colton (USA), Prof. Michael Schemper (Austria), Dr Jørgen Seltrup (UK), and Prof. John Whitehead (UK).

The annual general meeting of the ISCB is organised to coincide with the scientific meeting. Membership of the Society is drawn from over 30 countries worldwide and the number of members is over 700.



The ISCB also has 4 special **subcommittees** dealing with particular aspects of biostatistics:

A particular focus in recent years has been statistics in drug regulatory affairs. The terms of references and function for the **SEDREG** Subcommittee is to finalize as soon as possible the position paper being prepared by the former Executive Team members. A final edition of the paper approved by the Committee must be available before the end of 1996 at which time the Subcommittee should be disabled. The chairman of the ISCB subcommittee on Statistics in European Drug Regulation (**SEDREG**) is Prof. Wolfgang Köpcke, University of Münster, Germany.

The 3 other new subcommittees are on:

Fraud: The Subcommittee will have the following goals: 1. to investigate the role of biostatistics in the prevention and detection of fraud in clinical research, and 2. to promote the role of appropriate biostatistical contributions in the assessment of misconduct. The Subcommittee will produce a position paper reflecting the opinions of its members. The chairman is Dr Marc Buyse (Belgium).

Statistics in Regulatory Affairs: this subcommittee will track the development in regulatory requirements and ... The Subcommittee is chaired by Prof. Helmut Schäfer of Institute of Medical Biometry, Marburg (Germany).

Education: The subcommittee will assess the feasibility of organising a one or two day course on contemporary methods in Clinical Biostatistics which will involve several members as lecturers and be presented in locations represented by the Society. This includes assessment of costs and organisation of such a course. Once feasibility is assessed, this sub-committee will be responsible for planning the course curriculum and selecting lecturers. The financial role of ISCB should be considered. The sub-committee will also receive requests from members that this course be given at their location and evaluate them. It is anticipated that the first site at which the course will be presented is Barcelona, Spain. Chairman: Mike Campbell (UK).



The Society publishes a **newsletter** thrice a year. The editor is Dr David Warne, Chemin Frank-Thomas 32, CH-1208 Genève, Switzerland. Items for inclusion in the Newsletter should be sent to him (if possible on a 3.5" disk, Word6 format or text, or email on:

100557.2260@compuserve.com).

Membership of the Society is open to all with an interest in biostatistics. The current annual (to 31 December 1997) Ordinary membership fee is £15. The Full-time Student Membership fee is £7.50. Members can also choose to receive *Statistics in Medicine* at a reduced cost (see above), and benefit from the reduced conference fee, at least £15 less than for non-members.

Subscribe

Applications for membership should be addressed to:



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1997
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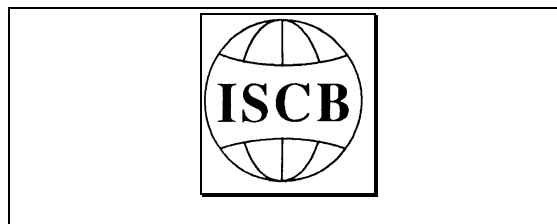
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Calendar

12-15 February 1997

Geneva, SWITZERLAND

The Population Approach for measuring and managing variability in response, concentration and dose
Info: L. Ballant, Dep't of Psychiatry, 47 rue du XXX1 Décembre, CH-1207 Genève, Switzerland
Tel: +41 22 718 4696, fax: +41 22 718 4699, email: BALANT@cmu.unige.ch

3-6 March 1997

Heidelberg, GERMANY

9th Conference on the Scientific Use of Statistical Software (SoftStat'97)
Info: ZUMA, PO Box 122155, D-68072 Mannheim, Germany
Tel: +49 621 1246 174, Fax: +49 621 1246 100, email: sofstat@zumz-mannheim.de
WWW: <http://www.social-science-geis.de/sofstat.html/>

19-21 May 1997

Indiana, USA

20th Annual Midwest Biopharmaceutical Statistics Workshop
Info: M. Ames, H3-M2516, Hoechst Marion Roussel, PO Box 9627, Kansas City, MO 64134-0627, USA
Tel: +1 816 966 5303, fax: +1 816 966 5778, email: mikames@hmri.com

6-10 July 1997

Boston, USA

ISCB18 (Joint meeting with Society for Clinical Trials)
Info: Mary Burke, Joint Meeting ISCB/SCT, 600 Wyndhurst Ave., Suite 112, Baltimore, MD 21210 U.S.A.
Tel: +1 410 433 4722, Fax: +1 410 435 8631,
email: sctbalt@aol.com, WWW: <http://members.aol.com/sctbalt>.

22-25 July 1997

Leicester, ENGLAND-UK

Burning Issues in Medical Statistics
Info: B. Teather, Exec. Secretary BIMS Conference, Dep't of Medical Statistics, De Montfort University,
Leicester LE1 9BH, England-UK
Fax: +44 116 250 6114, email: bte@dmu.ac.uk

8-12 September 1997

Fredericton, NB, CANADA

Annual Meeting of the Statistical Society of Canada
Info: R.A. Mureika, Dep't of Mathematics and Statistics, The University of New Brunswick,
PO Box 4400, Fredericton, NB, E3B 5A3, Canada
email: mureika@math.unb.ca

15-16 September 1997

Paris, FRANCE

ASU-SSF '97
Info: B. Scherrer, Institute de Recherche Jouveinal, 3-9 Rue de la Loge, F-94265 Fresnes Cedex, France
Fax: +33 1 40967691

August 1998

Dundee, SCOTLAND-UK

ISCB19
Info: Andrew Lawson, University of Abertay Dundee, Statistics Division, School of Maths., Bell Street,
Dundee DD1 1HG, Scotland-UK
Tel: +44 1382 308604, Fax: +44 1382 308877, email: MCTAL@tay.ac.uk

Summers 1999 & 2000

Heidelberg, GERMANY & Trento, ITALY

ISCB20 & ISCB21
Info: ISCB Permanent Office

