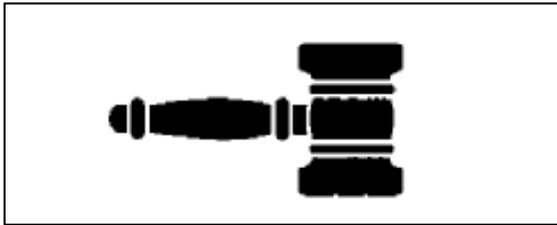

SCT Newsletter

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SCT President's Corner

by John Lachin

While the scientific structure of a clinical trial has changed little since the earliest multi-center trials of the 1940's, the way we go about organizing, conducting, evaluating, monitoring and publishing trials is continuing to evolve. All aspects of clinical trials now receive rigorous scrutiny from an increasingly sophisticated media and public, as well as the scientific community; and the regulations under which trials are conducted are ever changing. With each passing day these developments make the Society increasingly important to our members and raise new challenges. The Executive Committee has begun to consider how the Society can best meet these challenges in a changing world.

One of the most ubiquitous elements of life today is the internet. It is clear that one of the most important vehicles available to the society to meet these needs is the www. To that end, we have begun to consider how best to restructure the Society web site, or web presence; not so much the appearance as its role and content. We have established a new Web Editorial Committee under the leadership of President-elect Stephen George that will report directly to the Executive Committee. The immediate need is to set policy for establishing links and adding material to the Society's site.

In the long-term, we also need to consider as a Society how we can best meet the needs of the membership. One option would be to take a more proactive stance and to use the web and the journal *Controlled Clinical Trials* to provide the membership with updates on current trends in clinical trials, or thoughtful reports on current issues of the day, such as the impact of the Health Insurance Portability and Accountability Act on the conduct of clinical trials. To do so, however, would require that the Society, meaning we the members, be prepared to contribute our time, effort and resources to the identification of important topics and the development of such reports. We would appreciate your thoughts on these issues.

The new Web Editorial Committee will work closely with the Web support group under the leadership of Herman Mitchell (hmittell@rhoworld.com). Herman's eclectic group has provided outstanding technical support, but would welcome the participation of additional web programmers to help distribute the work load. Members with knowledge of systems written in Cold Fusion built over MS Access Databases could be of great assistance.

This year is also an especially busy year for the Publications Committee. Under the leadership of Dennis Dixon, the committee is negotiating a renewal of our contract with Elsevier North Holland for our continued sponsorship of *Controlled Clinical Trials*. In addition the Committee is conducting a search for a new editor of *Controlled Clinical Trials* to succeed Jim Neaton, who will be completing his term as Editor next year. Thanks to Dennis this process is well underway. Our many thanks to Jim for his outstanding service as Editor.

This year marks another in the five year cycle of joint meetings of the Society with the International Society for Clinical Biostatistics, to be held July 2003 in London. Both Societies were founded about the same time by individuals who shared a commitment to the science of clinical trials.

Having attended the prior joint meetings, I find that the joint meetings serve to energize the membership of both societies, as well as providing opportunities to renew old and establish new friendships. Co-chairs Mary Foulkes (SCT) and Deborah Ashby (ISCB) and their joint Program Committee have organized an outstanding meeting for 2003. Bob Byington and the Education Committee are also organizing another group of outstanding pre-conference workshops.

For those who mentor graduate students, I hope that you will encourage your students to submit an application for the Thomas Chalmers Student Scholarship Award. I also hope that all members will encourage their colleagues, especially those who are junior, to become members of the Society for Clinical Trials. New members, especially those who are now embarking on their careers, are the future of the society.

Marie Diener-West (mdiener@jhsp.edu) has agreed to chair the Nominations Committee for this year and is now entertaining nominations for officers and members of the Board of Directors.

Finally, I hope that all of you will join me in thanking past-president Janet Wittes, all current and past officers committee chairs, committee members and board members for your commitment and support of the society. I hope to see all of you in London in July.

ISCB/SCT 2003: Program Committee Update

By Mary A. Foulkes

The July 20-24, 2003 joint meeting will mark the 24th annual meeting for the SCT and for the International Society for Clinical Biostatistics (ISCB), as well as the 25th anniversary of the founding of each of these Societies.

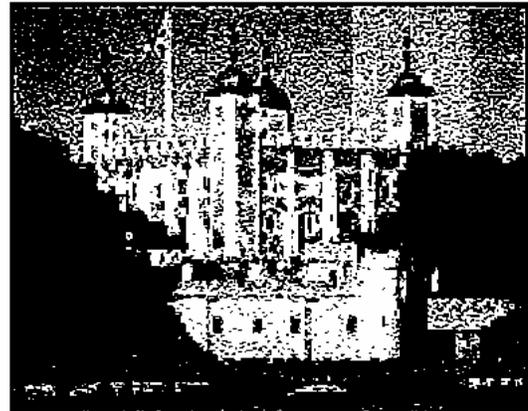
The incoming Society presidents, Maria Grazia Valsecchi (ISCB) and John Lachin (SCT), have invited as the keynote speaker for the conference Professor Stephen Senn, Department of Statistical Science, University College London. His keynote lecture, titled "Added Values", which he has abstracted:

“As ye randomise, so shall ye analyse,” is one way of describing Fisher's defense of randomisation. Yet, when it comes to clinical trials we nearly always randomise but we rarely analyse the way we randomise and Fisher himself was no exception. Here I consider whether randomisation inference in clinical trials is dead and whether modelling rules the day, whether minimisation is an acceptable procedure and the propensity score is an acceptable device and to what extent trialists confuse experiments with surveys. It will be maintained that a number of different possible purposes of clinical trials have been confused because in the case of the general linear model, under strong additivity, they can all be satisfied by a single analysis. More generally, however, this is not the case. The field of binary equivalence is an area that brings these conflicts to a head and will be briefly considered. It may be that more explicit declaration of the purpose of an analysis would be helpful in avoiding confusion.”

Invited sessions will include:

- "Recent Developments in Estimating Causal Effects" organized by John Carlin
- "Joint modeling of markers and event data" organized by Daniel Commenges
- "Modeling versus meta-analysis" organized by Jim Slattery
- "Adaptive designs in clinical trials" organized by Gordon Lan
- "International differences in clinical trial results" organized by Frank Rockhold and Stuart Pocock
- "Design, conduct and analysis of surgical trials" organized by Marion Campbell

The half day Mini-Symposium on Thursday, July 24th, will be on "Data Monitoring Approaches" organized by Doug Altman and Susan Ellenberg.



The Tower of London

There will also be social program and conference dinner. Watch the ISCB and SCT websites for more details as information becomes available.

The joint Program Committee has been working diligently to construct a diverse, stimulating, and innovative program. The Committee will finish off this program with the contributions from participants from both Societies, which are already being submitted, see www.sctweb.org. We are particularly interested in abstracts relating to multinational clinical trials.

There is still time to submit your contribution (Deadline: January 15, 2003). Join us in London, and you will surely agree with Samuel Johnson, "When a man is tired of London, he is tired of life"!!

SCT Education Committee Update

by Bob Byington

This year the SCT Education Committee has on it Bob Byington (Chair), Bill Blackwelder, Tim Church, Nicole Close, Rick Ferris, Virginia Howard, Annemarie Lopina and Wasima Rida. Our primary current activity is finalizing the program for the Pre-Conference Workshops to be held on July 20, 2003 in London before the 3rd Joint Meeting of SCT and ISCB.

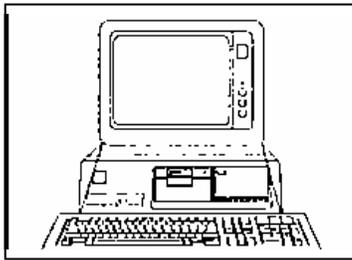
We are anticipating an exciting, more international flavor to the Workshops this year. As usual, we will have workshops aimed at people who are new to clinical trials and wish to learn the general principles or trials. We also plan on having workshops on statistical issues, data management issues, and trial monitoring issues. The final details will be described in the materials you all will be receiving in mid-Winter when you receive instructions on how to register for the meeting.

FDA Draft Guidance on Data Monitoring Committees

by Susan Ellenberg

Last fall, the FDA's three Centers for human medical products--Center for Biologics Evaluation and Research, Center for Devices and Radiological Health and Center for Drug Evaluation and Research--jointly issued a draft guidance document on clinical trial data monitoring committees (DMCs). The document discussed operational issues as well as principles for determining whether a trial should have an independent DMC.

After a period of open public comment, FDA staff are working on a revised document that should be available sometime in 2003. The current draft can be found at: www.fda.gov/cber/gdlns.clindatmon.htm.



Society for Clinical Trials Web Site Update

by Herman Mitchell

The Society web site is located at:
<http://www.sctweb.org>

The web site includes information about the purpose and objectives of the SCT. The current officers of the society and current members of the board of directors are included. Each committee of the Society is listed, along with the responsibilities of that committee, the current chair of that committee, and email contact information for that chair.

The web site now provides information regarding the July 2003 joint meeting in London with the ISCB. Abstracts for the SCT/ISCB meeting can be submitted on-line or the abstract form can be printed from the web site for submission by mail.

The web site includes a link to our meeting hotel, the Hilton London Metropole. Information regarding hotel rates and registration will be available in early 2003. A new feature of the web site allows membership dues to be paid on-line. On-line payment for the 2003 meeting registration will also be available on-line early in 2003.



Student Scholarship Program

The Student Scholarship Program was established to stimulate student interest and research into issues related to the focus of the Society for Clinical Trials.

Students are invited to submit abstracts, along with short manuscripts, in clinical trial related issues such as

- Study design and data analysis
- Meta-analysis
- Medical, ethical, or legal issues
- Data entry, management, and computing as it relates to clinical trials
- Review of the results or methods of a class of trials
- History of clinical trials

Note that the deadline for submissions is January 15, 2003. (Student scholarship abstracts may not be submitted on line.)

Three to five students will be named as presenters, and will have fees waived and travel and living expenses paid. The student judged to have the best presentation will receive in addition, the Thomas C Chalmers Student Scholarship Award of \$500. Details on student eligibility and the submission procedure are available on the SCT web site at www.sctweb.org. For more information, contact Student Scholarship Committee chair Steven Goodman, email: sgoodman@jhmi.edu or fax (410) 955-0859.

Notes from the Editor

If you would like to join the Society for Clinical Trials or receive additional information about the Society's 2003 Meeting, check the SCT web site at www.sctweb.org or contact Mary Burke at phone (410) 433-4722 or email address sctbalt@aol.com

If you have suggestions for this newsletter, please contact me, *SCT Newsletter* editor Jennifer Gassman in the Department of Biostatistics and Epidemiology at the Cleveland Clinic Foundation via email to gassmaj@ccf.org.