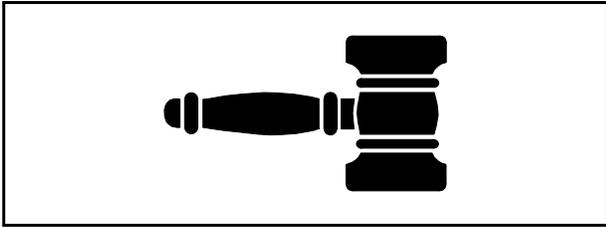

SCT Newsletter

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SCT President's Corner

by Barbara Hawkins

In Baltimore this week, the weather has been cool and drizzly as it was in Dundee, Scotland, at the end of August when I attended the 1998 annual meeting of the International Society for Biostatistics (ISCB). As part of that meeting, the ISCB Executive Committee discussed the possibility of a future joint meeting with the Society. The Executive Committees of the two societies tentatively have targeted 2003 for the next joint meeting. This choice would retain the six-year interval between joint meetings.

Possible venues in the United Kingdom have been discussed. Despite the appeal of Oxford and Cambridge, neither town has sufficient accommodations for a joint meeting. Other options are being explored, and we are soliciting suggestions for other locations in the U.K. (See page 2 of this *SCT Newsletter*.)

With the change in the weather, I already am looking forward to warm, sunny weather when we meet in Anaheim, California, on May 2-5, 1999. I also am looking forward to an excellent scientific program.

Steve Piantadosi and other members of the 1999 Program Committee met by telephone on October 6 to discuss invited plenary sessions and workshops. Many more ideas were proposed than one meeting can accommodate. However, so far the Program Committee has a paucity of data management topics under development. Suggestions should be sent to Steve Piantadosi or Steve Singer. Mary Burke reported that no abstracts have yet been received. The abstract deadline is December 1, 1998.

In addition to interim telephone conferences, the Program Committee has scheduled the program organization meeting for January 11, 1999, in Baltimore. At that meeting, the contributed sessions will be organized and scheduled in preparation for distribution of the preliminary program.

To celebrate the 20th anniversary of the Society, at the 1999 meeting, some of the founding members will make a "historical" presentation. Founding member Curt Meinert is organizing this session which will replace the traditional keynote address.

The Nominating Committee, chaired by Ted Karrison and composed of Sandy Forman, Kay Dickersin, Joe Collins, and Ken Schechtman, is working on the slate of candidates for President-Elect and members of the Board of Directors. Please forward your nominees to Ted or to another member of the Nominating Committee.

SCT President's Corner ***(continued)***

The Membership Committee, chaired by Susan Margitic, is completing analysis of data from the survey of 1998 annual meeting participants.

The Development Committee, chaired by Frank Rockhold, has been very active in planning for a new fundraising initiative for the Society.

If you would like to serve on these or another of the Society's committees, please contact the chairperson, a member of the Board of Directors, or me.

This is an exciting year for clinical trialists. Later this month, I will attend the clinical trials conference organized by the British Medical Association and the British Medical Journal to celebrate 50 years of modern randomized clinical trials. Information about that meeting appears on page 5 in this issue of the *SCT Newsletter*. Several members of the Society have been active in planning the program for that meeting and in preparing presentations.

Also this month Stuart Pocock will be participating in the 1998 Asian Clinical Trials Conference in Hong Kong. Information about this meeting is also given on page 5 in this issue of the *SCT Newsletter*.

Along with other members of the Board of Directors, I am eager to hear your suggestions regarding the annual meetings and other Society activities. I apologize to those of you who have tried to reach me by e-mail during recent months without success. You now should be able to reach me at

Bhawkins@jhmi.edu

Future SCT Dates, Suggestions for 2003 Location

In 2000, the SCT will meet from April 16 to 19 at the Royal York Hotel in Toronto, Ontario. Dates and locations for 2001 and 2002 have not yet been set.

In 2003, the SCT plans to meet jointly with the International Society for Clinical Biostatistics in Europe, probably in the United Kingdom. Blackpool and Brighton have been suggested. Oxford and Cambridge have been ruled out due to lack of appropriate meeting space. Holding the meeting in Ireland would be difficult because there are few Irish ISCB members to serve as a local organizing committee. If you have suggestions regarding the location of the 2003 joint meeting, send these by email to scbalt@aol.com with a subject line as "Location for 2003." Messages sent to scbalt on this subject will be shared with the President Barbara Hawkins and the Board of Directors.

Update on International Harmonization Documents

by Susan Ellenberg

An FDA guidance document entitled "E9: Statistical Principles for Clinical Trials" has recently been issued; its availability was announced in the Federal Register on September 16, 1998. This document is the product of a collaboration of industry and regulatory statisticians in the U.S., Europe and Japan. It is one of a number of guidance documents arising from the International Conference on Harmonization (ICH), an ongoing collaboration of industry and regulatory scientists in these 3 global regions. An earlier version of this document

International Harmonization Documents (continued)

was made available for public comment in May, 1997; a number of comments were received and the document was revised to account for many of these comments.

The purpose of the E9 document (the "E9" is part of the ICH numbering system) is to establish the importance of adhering to sound statistical principles in the conduct of clinical trials, and to provide guidance to sponsors of such research in this regard. This guidance document is also being published under the auspices of regulatory authorities in Europe and in Japan, and is intended to promote the consistent use of appropriate statistical methods and approaches in the increasingly multinational context of drug development.

The document is published in its entirety in the above-mentioned issue of the Federal Register. It can be downloaded and printed from the following web address:

www.fda.gov/cber/guidelines.htm

More detailed information on ICH and other guidance documents that have been issued under this collaboration can be found at: www.ifpma.org/ich1.html

Anaheim Program

The 20th Annual Meeting of the Society for Clinical Trials will be held at the Anaheim Marriott on May 2 to 5, 1999. Steven Piantadosi of Johns Hopkins University is the Program Committee Chair. Program Committee members include Dorothy Adams-Farnham, William Blackwelder, Jean Pierre Boissel, Gerrit DeBoer, Joseph Collins, Lloyd Fisher, Young Jack Lee, Joseph Pater, W. Joseph Shih, Steve Singer, Peter Thall, and Alicia

Toledano, as well as president Barbara Hawkins and president-elect Barry Davis.

Plans for the 1999 program are still in their early stages. If you have suggestions for the program, talk to one of the committee members or contact committee chair Steven Piantadosi by phone to (410) 966-4884, by fax to (410) 955-0859, or by email to steven.piantadosi@jhu.edu.

Abstract forms have been mailed to SCT members; **the abstract deadline is December 1**. If you are not a member and you need an abstract form or you would like to be placed on the list to receive meeting registration materials when they become available, contact Mary Burke at the SCT office by email to sctbalt@aol.com or by fax to (410) 435-8631.

Anaheim Marriott

The Anaheim Marriott, site of the 20th Annual Meeting of the Society for Clinical Trials, is in Anaheim, California.

This hotel has three restaurants (including a Pizza Hut) and two lounges. Guest rooms have coffee makers and two-line phones with data ports - what more could we ask for? There is an indoor pool, an outdoor pool, a whirlpool, a sauna, and a health club. Golf is available nearby at Anaheim Hills, Coyote Hills, or Pelican Hills.

This hotel, which has over 1000 rooms, is located 15 miles from the Orange County/John Wayne airport (SNA), 20 miles from the Long Beach Airport (LGB), 35



Anaheim Marriott (continued)

miles from the Los Angeles Airport (LAX), and two blocks from the entrance of Disneyland.

Adventurous SCT members may wish to visit some of the newer features at Disneyland, including the Indiana Jones Adventure (featuring rats, bats, poison darts, a river of lava, and 50 tons of rolling granite) and the Astro Orbiter, billed as "a starship trip past planets and constellations into the next millenium."

Student Scholarship Program

by Rick Chappell, Chairman

The 1998 Student Scholarship Program had 18 entries from all over the world. Seventeen students and one postdoctoral fellow entered from Canada, France, Russia, Italy, the United Kingdom, India, New Zealand, and the United States. The winners in 1998 were Jeffrey Blume of Johns Hopkins in Baltimore, Cedric Mahe of the Department de Biostatistique et Informatique Medical in Paris, and Wei Li of the Hopitaux de Lyon in Lyon, France. Wei Li won the Chalmers award as well.

Due to my sabbatical at the EORTC in Brussels from January through June 1998, Ted Karrison was interim chairman for this period. In addition, Ted has been on the committee for over a decade and served as its chairman for several years. This was his last year as a member and I would like to take the opportunity to express my gratitude. Thanks a lot, Ted; you have done more than your share.

I would also like to thank the following members of the Student Scholarship Committee: Fran LoPresti, George Chi,

Steven Goodman, Deborah Shapiro, William Henderson, Kenneth James, and Marie Diener-West.

On to new issues. I request your help in publicizing this contest to students at all levels as well as postdocs, residents, and fellows. Thanks. Here are the details:



Students enrolled in a degree program of an accredited college or university, post-doctoral fellows, and physicians enrolled in an accredited residency program are eligible to apply. The deadline is December 1st, 1998.

Students are invited to submit abstracts and short manuscripts (no more than three pages) on topics related to the design and analysis of trials; data entry, management, and computing as applied to clinical trials; review of the results or methods of a class of trials; or medical, legal, or ethical issues related to clinical trials. The three students with the best abstracts are asked to submit full manuscripts for review and to present their papers at the annual meeting, with all registration fees waived and travel and living expenses paid for by the Society (up to a \$1750 limit).

The student judged to have the best manuscript and presentation receives the Thomas C. Chalmers prize, a \$500.00 cash award. In addition, all three winners receive written comments from the review committee.

Questions or comments can be addressed to Rick Chappell by e-mail to chappell@stat.wisc.edu or by phone at (608) 263-5572

50 years of Clinical Trials - Past, Present and Future

An international multidisciplinary conference, Randomised Controlled Trials: 50 years of Clinical Trials - Past, Present and Future, will be held October 29 and 30, 1998, in Westminster Central Hall in London.

The aims of the conference are 1) to exchange knowledge and perspectives about the past, present, and future of therapeutic evaluation, 2) to create a dialogue among statisticians, clinical trialists, clinicians, historians, patients' representatives, and social scientists about the means and ends of clinical trials, and 3) to commemorate the 50th anniversary of the publications of the MRC Streptomycin Trial.

For further information about the conference, contact Jane Lewis at phone +171 - 383 6605, by fax at +171 -383 6663, or by email to JaneLewis@bma.org.uk

Asian Conference

J.P.E. Karlberg, Chairman

The Asian Clinical Trials Conference 1998 will be held from October 25 to 27, 1998, at the Hong Kong Convention and Exhibition Centre (HKCEC) in Hong Kong.

The conference is hosted by the Clinical Trials Centre of the Faculty of Medicine, The University of Hong Kong and the Clinical Trials and Epidemiology Research Unit of the National Medical Research Council, Singapore.

With the recent achievements made in commerce, science and technology, the practice of medicine is also becoming increasingly more sophisticated in Asian

countries. Clinicians and patients alike have begun to appreciate the need for evaluation of efficacy of treatment protocols originally developed in the West. The difference in disease patterns, environmental effects, and other local factors make it important to pursue this in different ethnic groups. The Conference will, for the first time, bring together experts to enhance communication, cooperation and quality of clinical trials in Asia. I look forward to meeting you in the Hong Kong Special Administrative Region in October 1998!

Pre-conference Courses in Hong Kong:

There will be two parallel pre-conference courses, Clinical Trials Research Methodology and Statistical Methods in Clinical Trials.

Asian Conference Program:

Sunday, October 25 - Disease Pattern Day

- Plenary Session: Disease Patterns in Asia
- Symposium: Therapeutical Response in Asians
- Free paper presentation
- Workshop: Drug Regulations & Development

Monday, October 26 - Trial Day

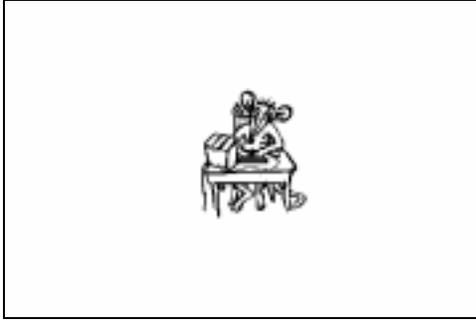
- Plenary Session: Research Ethics
- Symposium: MetaAnalyses
- Free paper presentation

Tuesday, October 27 - Method Day

- Plenary Session: Quality of Life
- Symposium: Statistical Issues,
- Workshop: Contract Research Organizations,
- The Black Pearl Lecture

For more information:

For more information about the Asian conference, please contact the Conference Secretariat at (852) 2866 7530 [fax] or at sigfmshk@netvigator.com [email] or at (852) 2527 8898 [phone].



SCT Web Site Update

by Herman Mitchell

The SCT Web Site Committee (a subcommittee of the SCT Publications Policy Committee) has received approval and funding from the Board of Directors of the SCT to enhance the Society's official web site which currently resides on AOL at:

<http://www.members.aol.com/sctbalt>

Under the direction of Fran Lopresti, a number of upgrades have been made to the Society's main administrative office systems in order to provide Mary Burke with a more current hardware and software platform. These upgrades should improve the efficiency of Mary's activities and facilitate a better linkage to the Society's new Web-based functionality.

The SCT has plans for several enhancements to the SCT Web site. The Web page will include:

- Capability for an on-line newsletter and current SCT activities,
- Current and detailed SCT Committee information, members and activities,
- A Web-based downloadable membership application for submission via email,
- A downloadable form to submit abstracts to the annual meeting,

To develop the structure for a Web accessible membership list, each SCT member will be asked for approval to include their name, telephone number and e-mail address for the web-based directory. This approval will be requested on the new SCT membership form.

A newly hired consultant will provide the basic structure for these enhancements and assists the Society in moving the Web site to a platform which can better support its growing needs and interactive capabilities. A volunteer group, headed by Herman Mitchell, chair of the Web Site Committee, is currently exploring further enhancements to the new web platform, including search capabilities for the membership lists, on-line meeting abstracts, job postings, and electronic submission of abstracts. This volunteer committee includes Sharon Bak, Scott Rushing, Ella Temprosa, and Fran LoPresti. The Web Site Committee is chaired by Herman Mitchell. If you have suggestions for the Web Site, send email to Herman Mitchell (hmitchell@rhoworld.com).

Notes from the Editor

To join the Society for Clinical Trials or to receive information about the 20th Annual Meeting in Anaheim in 1999, contact Mary Burke at (410) 435-8631 (FAX), (410) 433-4722 (phone), or sctbalt@aol.com (e-mail).

If you have suggestions for this newsletter, please send them to *SCT Newsletter* editor Jennifer Gassman in the Department of Biostatistics at the Cleveland Clinic Foundation, (216) 444-8023 (FAX) or jgassman@bio.ri.ccf.org (e-mail).
