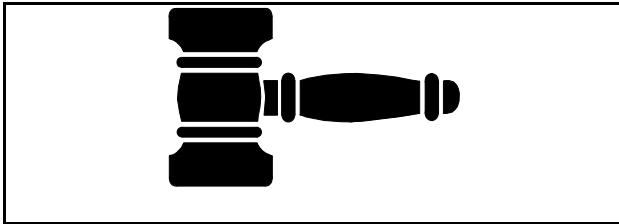

SCT Newsletter

Volume 12, Number 2

May 2003



SCT President's Corner

by John Lachin

I recently announced via e-mail to the membership of the society the exciting new development that the Society is launching a new journal *Clinical Trials: Journal of the Society for Clinical Trials*. Elsewhere in this newsletter Dennis Dixon, Chair of the Publications Committee, tells the story of how we came to reach this momentous decision, and Steve Goodman, the inaugural editor, describes his goals for the journal and issues a call for papers.

Our challenge as a Society is to work to ensure the success of the new journal. This will require that members contribute their scholarly work to the journal, and that we encourage our colleagues to do so. This will also require that we promote the new journal within our own University, agency or business. We encourage you to write to inform your librarian that as of January 2004 the Society will be sponsoring *Clinical Trials* and asking that your institution subscribe. Subscription details are provided in Steve Goodman's newsletter article.

Controlled Clinical Trials has established a sound and highly respected body of scholarship, thanks in large part to the scholarly contributions of our members and the diligent work of the present editor Jim Neaton and his predecessors Curtis Meinert and Janet Wittes. The Society is immensely grateful for their contributions to advance the science of clinical trials.

As my presidency comes to a close, I wish to thank the many committee chairs and members who have worked diligently to plan for another outstanding meeting, and for the future of the Society. In particular, I wish to again acknowledge the commitment and leadership of Dennis Dixon as he and his committee negotiated with Elsevier Science and Hodder-Arnold on the publication of the journal of the Society and the selection of the new Editor. I also thank the members of the Executive Committee and Board of Directors for their support.

I also welcome Stephen George as the next Pres-ident of the Society. Steve has been a great asset during the past year. Herein Steve presents some of the many challenges to the Society as we face the future of clinical trials. As we transition to new leadership, I especially wish to thank Joel Verter who has resigned after many years of service as Secretary of the Society. Joel has diligently recorded the minutes of various meetings and provided vital "institutional memory" in our discussions.

I hope that all of you will join us at our forthcoming meeting in London, jointly with the International Society of Clinical Biostatistics, as we explore the latest developments in the methodology of clinical trials and clinical biostatistics.

Clinical Trials: Journal of the Society for Clinical Trials

by Steve Goodman

For the Society's journal, these are the best of times and the worst of times. The reason for the best of times is clear; as of January, 2004, we will have a new journal with a new name, *Clinical Trials: Journal of the Society for Clinical Trials*, which more simply and accurately represents the actual range of the journal; we have a new publisher (Arnold) that is creative and eager to do whatever it takes to promote the journal (and thereby the society) in the right forums, and that is willing to put the resources into the journal and the editorial office to achieve what I will describe below; we now own the rights to journal and its contents; and with a fresh start and an expanded scope we have excited many in the clinical trials community both inside and outside the society. I will defer the "worst of times" missive until the end - please hold on until then.

In the relatively short time since this new journal has been announced, we have been able to assemble an extraordinary editorial team, some of whose names may not be familiar to all of you because the boards, like the field itself, spans many disciplines.

Clinical Trials: Journal (continued)

For the Advisory Board, we have several former Society presidents: Dave DeMets, Janet Wittes and Bob Temple. To this core has been added Iain Chalmers, David Sackett, Julie Buring, Don Berry, and Janet Darbyshire.

For the editorial board, we have a wonderful smorgasbord of creativity and technical expertise, with Doug Altman, Hilda Bastian, Colin Begg, Jesse Berlin, Baruch Brody, Marc Buyse, Rob Califf, Mike Clarke, Steve Cole, Jeff Cutler, Kay Dickersin, Matthias Egger, Diana Elbourne, Susan Ellenberg, Diane Fairclough, Dianne Finkelstein, Nancy Geller, Catherine Hill, John Ioannidis, Alejandro Jadad, Ted Karrison, Phil Lavori, Richard Lilford, Tom Louis, Harry Marks, Steve Piantadosi, Ron Prineas, David Schoenfield, Steven Self, Joe Shih, Steve Snappin, Jeremy Sugarman, and Peter Thall. A few others will be added to both lists, but it should be apparent that we have a rich array of talents on the boards that will hopefully soon be reflected on the pages of the new journal.

To all of these people we owe very hearty thanks, as there was not a single member of this board who did not sign on with an already over-filled plate, not a few with sincere cries of pain about another offer “too good to refuse” coming over the transom. Their generous agreement to serve in these roles was a much-needed vote of confidence in - and real commitment to - the new journal.

I am hoping that you all will be pleased with the look of the new journal, which has a design that is clean, serious and bold. But more important than the skin is that which lies beneath. While building on the same methodologic foundation that has been a strength of the Society’s journal in the past, we are hoping to attract articles from other communities that are writing things that we want to read, albeit currently mainly in other venues. These include articles on the intersection of clinical trials with bioethics, evidence synthesis, quality-of-life, policy, history, patient involvement, training and teaching, health policy, regulation and law, evidence-based medicine, informatics, and several other areas. All of these disciplines have been represented on the pages of the Society’s journal, but the awareness of many in these communities of the Society journal as an outlet for their work could still be greatly improved. I am hoping to achieve this through more intensive and far-ranging outreach, networking by our advisory and editorial boards, and word of mouth from all of you.

My goal is to make *Clinical Trials* the premier multidisciplinary journal within which are conducted discussions of all issues related to the design, analysis, conduct, ethics, synthesis, history, oversight and impact of clinical trials. I would also like to see active debate on its pages, and on the web, surrounding these topics. I would also like to have more special issues related to themes and conference proceedings of interest to the clinical trials community.

Now, the worst of times. While I am very excited by and have few doubts about the long-term prospects of *Clinical Trials*, the publisher negotiations left us with a very short time-line for the first issue, and because we are a new journal, no queue. It is a timeline that would be challenging

even for an established journal, no less for one that is barely announced. This is when society affiliation must make a difference. For this journal to be successful from Day 1, we need each member of this society to:

1) Request that your library subscribe to the new journal starting in January. (Relevant information is listed below.) It may be worth noting in this request whether they have subscribed to the Society’s journal in the past (i.e. *Controlled Clinical Trials*), and emphasizing that our new journal is expected to continue with the same quality, emphasis, subscriber base, and demand from the biomedical community.



2) Mention the journal and encourage submissions from colleagues (or yourselves!) that might have manuscripts contemplated or close to submission on clinical trial-related topics. If they submit soon, they could see their papers in print sooner than they would in any alternative journal. .

3) Keep your eyes and ears out and alert me (sgoodman@jhmi.edu) to any talks, conference presentations, topics, controversies, and other issues that might lend themselves to journal presentation and discussion, tutorials, commentaries or the like.

I very much look forward and appreciate the opportunity to create a journal that the Society will be proud of, and that will serve its needs and those of the broader clinical trials community. Curt Meinert, Janet Wittes, and Jim Neaton have provided a sound foundation and strong shoulders to stand on, but now that we are starting anew, I need the shoulders of all of you as well to help us create a journal for this next century of clinical trials.

Submissions and Institutional subscriptions:

Submissions should be electronic (in PDF or MS Word compatible format), to: clinicaltrials@jhmi.edu (The editor can be emailed at sgoodman@jhmi.edu.)

The website, which is not yet up, will be at www.sctjournal.com Institutional subscriptions can be requested from Arnold journals and Turpin Distributors at: subscriptions@turpinltd.com

Telephone: +44 (0) 1462 488900;

Fax: +44 (0) 1462 480947;

Address: Turpin Distribution Services Ltd, Blackhouse Road, Letchworth, Herts SG6 1HN, UK.

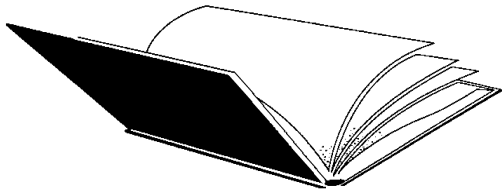
ISSN: 1740-7745; Online ISSN: 1740- 7753

SCT Publications Committee Report

by Dennis Dixon

As noted in SCT President John Lachin's column and in Steve Goodman's article above, the Society has agreed to start publication of a new journal, *Clinical Trials: Journal of the Society for Clinical Trials*, jointly with Edward Arnold (Publishers) Limited in January of 2004. Simultaneously the Society notified Elsevier Science that we would end our sponsorship of *Controlled Clinical Trials* at that time. Further, Steven N. Goodman of the Johns Hopkins University has accepted appointment to be the founding editor of *Clinical Trials*. (Everyone on the Society's e-mail distribution list will have already received this news.)

These actions complete a process that began almost a year ago; if you are at all curious about twists and turns on that path, please read on. In a companion piece just prior to this article in this *SCT Newsletter*, Goodman describes his plans and ambitions for the new journal.



The Publications Committee began to carry out its formal assignment, to manage the search for a new editor of *Controlled Clinical Trials*, last July. Professor James D. Neaton's editorial term, marked by notable innovation and distinction, will end in December 2003. The Committee formulated a timetable that we hoped would get a new editor named very early in 2003.

Committee members worked individually to assemble lists of candidates. As a group we then went through multiple rounds of list pruning and ranking. It was surprising, considering the overall talent pool, that Steve Goodman emerged as the leading candidate rather quickly. Of course his qualifications are exceptional: advanced degrees in medicine, biostatistics, and epidemiology; appointments concurrently in oncology, pediatrics, biostatistics, and epidemiology at Hopkins; significant previous editorial experience; and dedication to the Society as evidenced by his membership on the Board of Directors and Student Scholarship Committee, on which he currently serves as chair.

Before the search process reached its formal conclusion with confirmation by the Board, however, the path took an unexpected turn. As usual, review and renegotiation of the Society's legal agreement with Elsevier Science, Inc., proceeded in tandem with the editorial search. We began to realize that the Society and Elsevier had different visions for *Controlled Clinical Trials* and that subsequent discussions among the parties might not lead to a mutually satisfactory solution.

By pure coincidence, an Arnold representative approached the Society at the end of October 2002. The company had decided to expand its publications in science and research

methodology, especially in biomedical research, and inquired whether the Society would have any interest in considering a change in publisher for the official journal of the Society. Thus began a series of discussions and face-to-face meetings, among ourselves and with both publishers, that continued until the Committee unanimously adopted the following resolution on March 21, 2003: "The Society for Clinical Trials Publications Committee recommends that the Society not renew its agreement with Elsevier for sponsorship of *Controlled Clinical Trials*. The current agreement expires on 31 December 2003. The Committee further recommends that the Society take all necessary steps to begin publication of a new journal, to be called *Clinical Trials*, in partnership with Edward Arnold." (The Board later decided to append "*Journal of the Society for Clinical Trials*" to the name.)

Neither the Committee nor the Board of Directors made their decisions lightly; after all, the partnership with Elsevier has lasted for 24 exciting and fruitful years. The Society is justifiably proud of its role in the growth and impact of *Controlled Clinical Trials*. Looking forward, however, the prospects for even greater success seem brighter with a new journal, working with a new partner. Of course this future success depends, among other things, on the vigorous support of the Society's members, not only by submitting their best manuscripts to the journal (and responding to the editor's requests to help evaluate manuscripts submitted by others), but also in helping to build the journal's subscriber lists, both personal and institutional. Along these lines, you can expect to see further correspondence and communication both from the Society and from Arnold in the coming weeks.

The Publications Committee, with members Bob Byington, Kay Dickersin, Herman Mitchell, Jeff Sloan, and Janet Wittes, and ex-officio members Jennifer Gassman, Steve George, John Lachin, and Jim Neaton, are extremely pleased our efforts have led to such promising conclusions for the Society. We greatly appreciate the support from the Board and, especially, the Executive Committee, which participated very actively over a period of months. Finally, we are only more enthusiastic about our recommendation for editor, Steve Goodman, who has shown, through his energetic and creative participation in the deliberations, that he will surely continue the very distinguished record of the Society's editorial appointments.

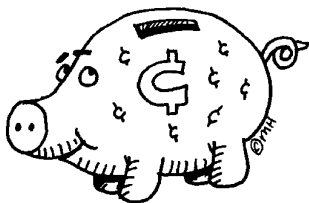


Student Scholarship Program

by *Steve Goodman*

This year's student scholarship program, conducted in collaboration with the ISCB group headed by Marie Reilly, was a great success, as will be apparent from the presentations and posters in London. We received over 30 submissions, and almost the top half were all of presentable quality. Four winners were chosen, with difficulty, and they will present their work in the student scholarship session in London. Two additional honorable mentions were selected, who will present their work as posters. The winners were Jiang Qi (Temple/Merck Labs, Advisors: Boris Iglewicz, Steve Snapinn), Meredith Goldwasser (Harvard, Advisor: Michael Hughes), Hui Xie (Columbia, Advisor: Dan Heitjan), and An-Wen Chan (Oxford, Advisor: Doug Altman). Honorable mentions went to Lu Zheng (Harvard, Advisor: Marv Zelen) and Mei-Hsiu Chen (Brown, Advisor: Constantine Gatsonis).

Thanks go to the members of the SCT committee who spent time evaluating the many excellent submissions: Marie Diener-West, Michael Hughes, and Bill Rosenberger. Thanks also to Marie Reilly of the ISCB and her raters for what turned out to be a very smooth joint enterprise. Please look for the session right before lunch on Monday, July 21, and support both the students and the program by attending. This will be the first professional exposure of this magnitude for most of the students, and having a good audience can make a tremendous difference. It is an interesting and eclectic assortment of papers, with a little something for everyone.



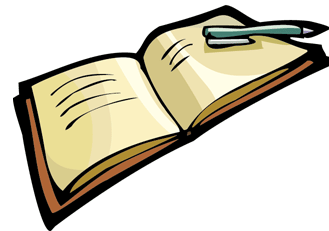
Development Committee progress

by *Fran LoPresti*

The Development Committee and the Board of Directors have been busy soliciting funding to support SCT activities. These include support for the Student Scholarship program, the SCT travel fund, SCT web site development, SCT infrastructure projects, and defraying costs for SCT meeting receptions.

To date, we have collected \$10,000. We would like to increase this amount to support the joint meeting this year. Please see our list of 2003 sponsors at the Society web site www.sctweb.org

The Society is grateful for the participation of each of our sponsors. If you have any suggestions for potential donors or would like to be on the committee, please send e-mail: FFLoPresti@Magellanhealth.com



Education Committee workshops

by *Bob Byington*

The SCT Education Committee includes Bob Byington (Chair), Bill Blackwelder, Tim Church, Nicole Close, Stephen Evans, Rick Ferris, Virginia Howard, Annemarie Lopina and Wasima Rida.

Five pre-conference workshops are planned for Sunday, July 20, 2003. These include:

Workshop I: Issues and Controversies in Data Analysis

Workshop II: Sequential Monitoring: Practical Implementation of Sequential Designs for Phase III Clinical Trials.

Workshop III: Coping with Missing Outcome Data

Workshop IV: Essentials of Clinical Trials

Workshop V: Statistical Validation of Surrogate Endpoints in Clinical Trials

The cost for pre-registration for a pre-conference workshop is \$125. Pre-registration is highly recommended. If there are any remaining openings for these workshops, on-site registration will be \$175.



Plans for the ISCB/SCT Meeting

*Program Chairs Deborah Ashby (UK)
and Mary Foulkes (USA)*

The London Eye, which has graced our conference brochures and preliminary programme, is the landmark on the north bank of the Thames. Selection of the London Eye was designed to catch your eye and attract you to the Joint ISCB/SCT conference in London, 20-24 July.

The London Eye contains 32 enclosed glass passenger capsules on the outside of the wheel carrying over 15,000 passengers per day. It reaches a height of 135 metres from which you can see 25 miles in any direction (on a non-foggy day). You can appreciate why the London Eye is the perfect visual analogy for the farsighted ISCB/SCT conference.

Approximately 400 contributed works have been packed (both chronologically and physically) into a busy Joint ISCB/SCT conference programme. Plan to arrive early at the London Metropole Hilton Sunday, 19 July for the pre-conference workshops, and join Stephen Senn as his Keynote Address opens the programme on Monday. After numerous informative invited and contributed sessions, cap a whirlwind week with a half-day minisymposium on Clinical Trial Data Monitoring.

A half day reserved for excursions is retained from the ISCB programme structure, so your Tuesday afternoon will be open for a variety of excursions.

Any spare moments remaining during your London sojourn can take advantage of the conference location, near Marlybone and Edgware Roads, and just north of Hyde Park. In the near vicinity are:

The Open Air Theatre in Regent's Park

(www.openairtheatre.org)

Madame Tussaud's

(www.madame-tussauds.com/site/london/frontdoor.htm)

Sherlock Holmes Museum

(www.sherlock-holmes.co.uk)

The British Museum

(www.thebritishmuseum.ac.uk/)

Theatre lovers can rely for the latest reviews and news on the Society of London Theatre (www.theatre-access.co.uk/) and their Half-Price Ticket booth in Leicester Square (home.clara.net/rap/half/).

Information on registering for the meeting and making hotel reservations at the Hilton Metropole are available on the Society's web site, www.sctweb.org

Talley-ho!

From the President-Elect

by Stephen L. George, President-Elect

In a recent report from the Institute of Medicine on the current status of clinical research¹, the authors state: "The context of clinical research is increasingly encumbered by high costs, slow results, lack of funding, regulatory burdens, fragmented infrastructure, incompatible databases, and a shortage of qualified investigators and willing participants." For a society whose focus is on enhancing the theory and methods of clinical trials, this assessment is sobering and disturbing. At the same time that the need for well-designed and well-executed trials is increasing, the number and types of impediments to conducting these trials are also increasing. In addition, some well-publicized failures of the systems set up to protect participants in trials and some egregious cases of scientific misconduct have served to undermine and weaken the public trust in clinical trials^{2,3}.

Because of these factors, we are faced with enormous challenges in maintaining and strengthening the clinical trials enterprise. The Society for Clinical Trials is well-positioned to be a major player in meeting these challenges, but it won't happen unless we make the effort. As one example, the media, both broadcast and print, extensively cover high-profile clinical trials with uneven success in conveying the results, and the debates about the results, in a balanced fashion. The Society is not often asked to participate in these discussions despite our mission and the strength of our membership. We should work to increase the visibility and status of the Society so that we are at the forefront of the public discussion of specific trials and the general issues raised by these trials. This will require a more pro-active approach toward addressing the more topical issues in clinical trials, outside of the usual forums of our journal and our meetings. It won't be easy, but we should make the effort.

Reference List

1. Sung, N. S., Crowley, W. F., Jr., Genel, M., Salber, P., Sandy, L., Sherwood, L. M., Johnson, S. B., Catanese, V., Tilson, H., Getz, K., Larson, E. L., Scheinberg, D., Reece, E. A., Slavkin, H., Dobs, A., Grebb, J., Martinez, R. A., Korn, A., and Rimoin, D. Central challenges facing the national clinical research enterprise. *JAMA*, 289: 1278-1287, 2003.
2. George, S. L. Perspectives on scientific misconduct and fraud in clinical trials. *Chance*, 10: 3-5, 1997.
3. Antman, K. Randomized trials of high-dose chemotherapy in breast cancer: fraud, the press and the data (or lessons learned in medical policy governing clinical research). *Transactions of the American Clinical & Climatological Association*, 113: 56-66, 2002.

SCT 2004 Program

by Ted Karrison

You are probably still making plans for the joint ISCB/SCT meeting this summer, but it's not too early to begin thinking about 2004. Next year's meeting will be held May 23 to May 26 in New Orleans, Louisiana. A call for abstracts will go out in early August of this year. This will be the 25th anniversary meeting of the Society, and so it should be quite an exciting time! The Program Committee for 2004 has been assembled, and consists of Dorothy Adams-Farnham, Thomas Capizzi, Rick Chappell, Emily Chew, Dorothea Collins, James Dignam, Lawrence Friedman, Jennifer Gassman, Michael Kutner, Ruth McBride, Sue Todd, and Edith Zang, in addition to myself (Chair) and Stephen George (President-Elect). Bob Byington has agreed to continue as chair of the Education Committee and will be organizing the Pre-Conference Workshops.

We are beginning to consider topics for invited sessions, and would welcome any suggestions from Society members. (You can e-mail them to me at tkarrison@health.bsd.uchicago.edu)

Notes from the Editor

If you would like to join the Society for Clinical Trials or receive additional information about the joint July 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.

If you are bringing a teenager with you to the London SCT/ISCB meeting this summer and your teen is interested in finding others with whom he or she can sightsee while you are at the meeting, send email to gassmaj@ccf.org. If several people contact me, I will set up an unofficial Yahoo groups email alias for young people planning to attend the meeting with a parent, so they can talk to each other via email before July.