

SCT President's Corner

by Eleanor McFadden

Welcome to our Fall 2007 Newsletter, the first produced by our Association Management Company, Fernley & Fernley. In partnership with Fernley & Fernley, we are at an exciting time in the Society's history as we begin to take a close look at our history, goals and achievements and work to position ourselves for the future. We hope that we can count on your input and support as we work to position ourselves as a Society that can influence policy and research in the 21st Century.

Fernley & Fernley is coordinating a Strategic Review of the Society, and this review process will continue for the foreseeable future. We encourage everyone's input and hope that you took the opportunity to participate in the on-line survey which was developed by the Membership Committee and circulated by email and on the web site in October. If you did not receive an email message about this survey, perhaps the email address on file with the SCT is out of date. Please make sure that you provide a current email address with your next membership renewal, or by contacting SCT, as we plan to use email more frequently for communications with members.

It is now five months since our excellent meeting in Montreal. This meeting was very well attended, with 660 registrations for the full meeting. We hope that we can exceed the attendance at the next meeting in St Louis, MO from May 18-21, 2008. The Program Committee, led by Ivan Chan and the Education Committee led by Domenic Reda are both hard at work developing an exciting program for this meeting. Please check the web-site towards the end of the year for information about the planned program. I hope to see you there.

One of our goals is to increase membership and to encourage more trialists to join and attend the meetings. It is an excellent forum to learn about all aspects of trials,



In this Issue...

President's Corner	pg. 1
SCT 2008 Meeting Update	pg. 2
Education Committee Update	pg. 3
From the Membership Committee	pg. 3
Nominations for 2008 SCT Fellows	pg. 4
NRAA Partners with Fernley & Fernley	pg. 5
SCT Members in the News	pg. 6
Upcoming Deadlines	pg. 7
Future Meeting Dates	pg. 7
Lots to Love in St. Louis	pg. 7
Notes from the Editor	pg. 7

not just statistics, or just data management. Anyone who attends a meeting or reads the SCT Journal (*Clinical Trials*) is going to learn about a broad spectrum of issues related to trials, and we encourage all of you to promote the Society, its Journal and its meetings to your colleagues.

The Society for Clinical Trials was originally established as an International Society, and, while the majority of Society members are from the United States, the number of members from other countries continues to grow. At the meeting in Montreal, we had attendees from 16 countries. As many trials become global in scope, it is important for us all to understand the procedures and issues in other parts of the world. We plan to have an international presence again at the meeting in St. Louis and would encourage members and non-members from outside the United States to submit abstracts for the meeting (deadline December 3rd, 2007). See the web site for submission details (www.sctweb.org).

Our Journal, *Clinical Trials*, provides a forum for publication of articles on all aspects of clinical trials, and we invite you all to submit manuscripts to the Journal for consideration. Recent publications include a series of invited papers on Targeted Therapy in Oncology (Vol 4, No. 2) and a series of articles on the Women's Health Initiative (Vol 4 No. 3). The Society has also published position papers in the journal and we would like suggestions from you for future papers of this kind. The publishing contract for the Journal is in renegotiation.

Our current contract was negotiated with Hodder-Arnold, who sold the Journal to Sage Publications. We are currently in negotiations with Sage over a new contract for Clinical Trials. Colin Begg, Kay Dickersin, Jim Neaton and Steve Goodman are all helping with this.

As you know, our new President-elect is Kay Dickersin. Kay and Jim Neaton (our Past President) have been working hard with me to move these activities forward and I would like to acknowledge their help. Our Committee Chairs are all actively pursuing the objectives of their respective Committees, and, as always, I am impressed by the time and commitment that is contributed on a vol-

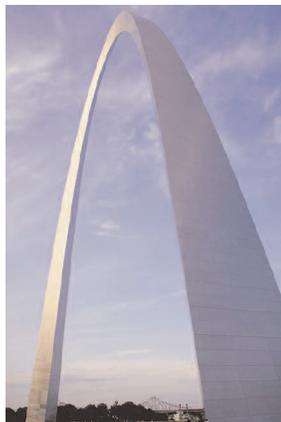
untary basis to ensuring the smooth running of the Society. Our new Board members (John Norrie, Dan Sargent and Virginia Howard) are all involved in the Strategic Planning Review and several other SCT activities. Finally, I would like to thank Mary Burke, Chris Donhauser, Steve Goodman and Anne Lindblad (Executive Director, Treasurer, Journal Editor and Secretary respectively) for all the work that they do to keep the Society running smoothly.

The Committee on Fellows is soliciting nominations of

SCT 2008 Meeting Update

By Ivan Chan - Program Committee Chair

The 28th Annual Meeting of the Society for Clinical Trials will be held at the Hyatt Regency St. Louis Hotel, St. Louis, Missouri, May 18-21, 2008. The SCT Program Committee kicked off the series of planning meetings in May during the SCT meeting in Montreal and has had several productive planning calls in recent months. The committee members include Abdel Babiker, Kay Dickersin, Frank (Xiaoyin) Fan, Susan Halabi, Gary Johnson, James Johnson, KyungMann Kim, Gordon Lan, Eleanor McFadden, James D. Neaton, John Norrie, Wendy Parulekar, Bruce Pihlstrom, Domenic Reda, Daniel Sargent, Christoph Seiler, Angela Smith, Paul Wakim.



I am excited to tell you that Professor Drummond Rennie, Professor of Medicine at the University of California at San Francisco and Deputy Editor of the Journal of the American Medical Association (JAMA) will start the meeting on Monday with his Keynote speech entitled "What Am I Worth? Take a Number! The Impact Factor and Much More Personal Problems".

On Tuesday, Professor Janet Darbyshire from the Medical Research Council (MRC) Clinical Trial Unit in the UK, and Deputy Director of the UK Clinical Research Network project, will present the Founder's Lecture entitled

"Creating a world class health service infrastructure to support clinical research – the UK experience."

As in the past, the program will also include plenary, invited, and contributed sessions. I am very happy to report that many SCT members have enthusiastically made

proposals for invited sessions, which cover a wide range of topics that should appeal to the diverse SCT membership. The Program Committee is finalizing these invited sessions as of this writing and the preliminary program will be posted on the Society web site as soon as possible.

Abstracts for contributed sessions are due on December 3, 2007 and may be submitted electronically by visiting the SCT Website (www.sctweb.org) or by mail to the central office. Relevant topics concern issues on the design, conduct, and analysis of clinical trials. In addition to statistical issues, topics including the use and evaluation of technology for data collection and data management are encouraged, as well as those related to study coordination and procedures for ensuring protocol adherence.

The Education Committee is also making plans to continue the popular and successful educational workshops. There should be something for everyone who is interested in clinical trials at the St. Louis meeting. Please mark your calendar, and I look forward to seeing you in St. Louis.

Education Committee Update

By Domenic Reda - SCT Education Committee Chair



The SCT Education Committee for 2007-2008 is chaired by Domenic Reda. We have expanded the Committee this year as we move towards offering more pre-conference workshops at the annual meeting and developing additional educational resources for our membership. Committee members include Denise Bonds, Nicole Close, Chris Coffey, Susan Cotter, Marta Gilson, Susan Halabi, Keri Hammel, Richard Kotz, John Lum, Michele Melia, Tom Moritz, Liz Murphy, Kristine Nelson, Wendy Parulekar, Domenic Reda, Yves Rosenberg, Wanda Umber, Julie Weston, and Carole White. Plans for the pre-conference workshop

program for the 2008 meeting in St. Louis are nearly complete. We anticipate having the most workshops ever offered with an all-star cast of presenters that includes Gordon Lan, Janet Wittes, Dan Sargent, Simon Day, David Sackett, Sylvan Green and Kay Dickersin. These workshops are selected to appeal to the diverse backgrounds of SCT membership and include topics such as:

- Fundamentals of Randomized Clinical Trials
- Interim Monitoring
- Trial and Site Management
- Non-inferiority Trials
- Biomarkers
- Electronic Data Acquisition
- Phase 2 Clinical Trials
- Data Monitoring Committees
- Safety Monitoring
- The Cochrane Collaboration

It is not too early to start thinking about the 2009 meeting in Atlanta. If you have a workshop proposal or are interested in being a member of the Committee, please contact Domenic Reda by e-mail at Domenic.Red@va.gov.

From the Membership Committee

By Michele Melia - SCT Membership Committee Chair

The Membership Committee would like to thank everyone who participated in the on-line member survey conducted October 2-23, 2007. The data from the survey will be summarized in a future issue of this newsletter and is being used to help develop a new strategic plan for the Society.

If you did not receive the e-mail with the link to the survey, your spam filter may have prevented you from receiving the e-mail. To ensure that you receive future e-mails sent out to Society members you should add the following e-mail address and domain name to your safe sender list: sctbalt@aol.com and @fernley.com. Also, if your e-mail address has changed since you last renewed your membership, the SCT office may not have your current e-mail address. You can e-mail your address corrections to Mary Burke at sctbalt@aol.com.

Nominations Sought for 2008 SCT Fellows

individuals to be elected Fellows of the Society for Clinical Trials. The next induction will take place at the May 2008 meeting in St. Louis during the opening plenary session of the meeting.



Nomination Process

Candidates for this honor must have been an SCT member for at least five of the last 10 years or for a total of at least 10 years. Each nominee will be evaluated by the Committee on the basis of contributions to the advancement of clinical trials in one or more of the following areas:

- Methodologic development
- Coordination, conduct, or leadership of individual clinical trials
- Education
- Ethics
- Promotion of a better understanding by the general public or the importance of randomized clinical trials
- Service to the Society

Any member of the Society may nominate a candidate. To do so, please assemble the following materials:

- Candidate's current curriculum vitae
- Three or more letters of support of the nomination from individuals qualified to describe the candidate's contributions to the Society. At least two of the letters should be from individuals at an institution, agency, or organization other than the candidate's.

Nomination packages may be submitted by email, fax, courier, or post to:

Barbara S. Hawkins, PhD
 Wilmer Clinical Trials and Biometry
 550 N. Broadway, 9th Floor, Room 930
 Baltimore, MD 21205-2010 U.S.A.
 1-410-955-0569 (fax) | bhawkins@jhmi.edu

All nominations should be received no later than January 31, 2008, for candidates to be considered for induction in 2008. Please send an email message whenever materials are being sent via courier, fax, or post.

Current Fellows of the Society

The following individuals were inducted as Fellows in 2006 and 2007:

2006

Peter Armitage
 David DeMets
 Katherine Detre (now deceased)
 Fred Ederer
 Susan Ellenberg
 Lloyd Fisher
 Bill Friedewald
 Curt Furberg
 2007

Michael Gent
 Mort Hawkins
 Genell Knatterud
 John Lachin
 Paul Meier
 Curt Meinert
 Stuart Pocock
 Robert Temple
 Janet Wittes

Evaluation of Candidates

Barry Davis
 Larry Friedman
 Sylvan Green

Barbara Hawkins
 Eleanor Schron
 George Williams

Candidates will be evaluated by the SCT Fellows Committee, which is made up primarily of current fellows; final selections will be made by the current fellows. The selections will be forwarded to the SCT Board of Directors for final approval. Individuals selected as fellows will be notified by March 31, 2008, so that they can arrange to be present at the 2008 Meeting.

Barbara S. Hawkins

For the 2007-2008 SCT Committee on Fellows:

Bob Byington
 (by invitation)
 Barry Davis
 Dave DeMets
 Susan Ellenberg
 Bill Friedewald
 Larry Friedman
 Sylvan Green

Barbara Hawkins, Chair
 Genell Knatterud
 John Lachin
 Curt Meinert
 Eleanor Schron
 George Williams
 Janet Wittes

As many of you know, the Society is now

SCT Partners with Fernley & Fernley, Inc.

By Elizabeth B. Franks



partnering with Fernley & Fernley, Inc., the oldest established association management company in

the country. The staff here at Fernley & Fernley is currently working with the SCT Board and Committees on some key projects:

- Strategic Planning
- Newsletter Production
- Membership Growth Strategies
- Site selection for future Annual Meetings

We are looking forward to expanding our work into other areas as well, including enhancements to the web-site. We will be working with SCT Executive Director Mary Burke as we transition in more management responsibilities over the next few years.

Here is some background on our firm:

An association management company (AMC) is a pool of skilled industry professionals who, based on the concept of shared resources, can provide management expertise and specialized administrative services to trade associations, healthcare organizations and professional societies in an efficient, cost effective manner.

The concept of an association management specialist was launched by our founder, T. James Fernley, over 120 years ago. The idea grew out of a need for leadership; and Mr. Fernley, then a hardware wholesaler and a member of the Hardware Merchants and Manufacturers Association of Philadelphia, stepped up to help manage the association.

T. James' son, Thomas A. Fernley, Sr., joined his father shortly thereafter, and the two quickly earned a reputation for exceptional organizational and leadership skills. By 1909, a number of other national associations had approached the Fernleys, requesting them to serve as their organization headquarters as well . . . and America's First Association Management Firm was born!

Since then, additional generations of the family have helped take the firm to new levels of client service, commitment and expertise. Today, a 4th generation, G.A. Taylor Fernley, serves as President & CEO. Fernley &

Fernley now provides management services to over 30 volunteer organizations and is recognized as one of the most distinguished association management companies in the nation.

Having received accreditation by both the Association Management Company Institute (AMC Institute) and the American Society of Association Executives (ASAE), exemplifies our commitment to quality and dedication to our industry.

As Fernley's Account Manager for SCT, I - Elizabeth Franks - will supervise all operations and functions that Fernley carries out for SCT. I have been with Fernley & Fernley for over 18 years and am experienced in all aspects of

association management, including meeting and convention planning, budget development, and public relations and marketing.

The beauty of partnering with an Association Management firm is that SCT is also served by the Fernley & Fernley Functional Support Network, including our Accounting, Meeting, Member Services, Convention Registration and Creative Services Departments.

With all of the professionals at Fernley & Fernley, SCT members can be confident that you have partnered with an association management company that will allow you to focus on your mission, while we manage the details.

At Fernley & Fernley we recognize that each of our clients is unique, with their own special needs. We work hard to understand each client's specific agenda and align our services and staff to meet those goals and objectives. We all look forward to getting to know you all better and learning more about the Society for Clinical Trial.

We are so happy to be working with SCT!
Please contact us at any time:

100 North 20th Street, 4th Floor
Philadelphia, PA 19103
PH: 215.564-3484

Fax: 215.564.2175

E-mail: Elizabeth Franks - efranks@fernley.com

SCT and Members in the News

Kay Dickersin elected to IOM

Congratulations to SCT President Elect **Kay Dickersin, Ph.D.**, who has been elected to the Institute of Medicine (IOM). Kay is Professor, Department of Epidemiology, and director, Center for Clinical Trials at the Johns Hopkins Bloomberg School of Public Health, in Baltimore. She was among the 65 New Members elected to the Institute in October. Total active membership in IOM is 1,538. New members are elected from among candidates nominated for their professional achievement and commitment to service.

"It is a great pleasure to welcome these distinguished and influential individuals to the Institute of Medicine," said IOM President Harvey V. Fineberg. "Members are elected through a highly selective process that recognizes people who have made major contributions to the advancement of the medical sciences, health care, and public health. Election is considered one of the highest honors in the fields of medicine and health."

Established in 1970 by the National Academy of Sciences, the Institute has become recognized as a national resource for independent, scientifically informed analysis and recommendations on human health issues. With their election, members make a commitment to devote a significant amount of volunteer time as members of IOM committees, which engage in a broad range of studies on health policy issues.

For more information, visit www.iom.edu.

Clinical Trials, SCT and Colin Begg in the News

The Society for Clinical Trials was prominently featured in an article in the October 2007 issue of *Scientific American*. The article, entitled "Experimental Drugs on Trial" by Beryl Lieff Benderly, explores the controversial "Abigail Alliance" lawsuit that challenges FDA's system of controlling access to experimental drugs. The article includes detailed background and history on the clinical trials process and references the SCT position paper on the Abigail Alliance proposals. Quoted in the article is SCT's Board Member, **Colin Begg**, Chair of Epidemiology and Biostatistics at Memorial Sloan-Kettering Cancer Center in New York City. Colin is Chair of the SCT Publications Committee and led the SCT working group that

"Allowing people to choose among unapproved chemicals would not mean that 'the patient would suddenly have access to the one drug out there' right for him and his condition, says Colin Begg, chair of epidemiology and biostatistics at Memorial Sloan-Kettering Cancer Center in New York City and of the Society for Clinical Trials."

From Scientific American, October 2007 issue – "Experimental Drugs on Trial"

wrote and published the position paper.

For more information, visit www.SciAm.com.

Upcoming Deadlines!

December 3 – Deadline for Abstracts for 29th Annual Meeting. Visit www.sctweb.org for submission forms.

January 31- Nominations due for SCT Fellows (See page 4 for details)

March 31- SCT Fellows will be Announced

Renew your annual investment in SCT! Dues invoices have been mailed. Pay promptly to ensure that your benefits, including your subscription to the Journal, are not interrupted. Pay your dues online at www.sctweb.org.

Save the Date!

Future SCT Meetings:

May 18 - May 21, 2008
29th Annual Meeting
Hyatt Regency St. Louis
St. Louis, MO

May 3 – 6, 2009
30th Annual Meeting
Omni Hotel at CNN
Center
Atlanta, Georgia

Lots to Love in St. Louis

Travel to St. Louis for the SCT meeting in May, 2008 and you'll find excellent education and networking benefits for all sections of the clinical trials community. As an added bonus, you also discover all that our host city has to offer.

Discover why St. Louis is...

Breathtaking - the Gateway Arch towers 630-feet over the mighty Mississippi River.

Historical – the city is rife with attractions that commemorate the achievements of explorers Lewis & Clark. Other historical sites include ancient Indian civilization of Cahokia Mounds, the Old Courthouse, Black World History Museum and Faust Historic Village.

Kid Friendly - Attractions like the Magic House, the City Museum and Six Flags St. Louis will entertain children of all ages.

Naturally Beautiful - Forest Park features 1,300 acres of lakes, walking paths and attractions. The Missouri Botanical Garden is one of the world's top public gardens.

Affordable – St. Louis features an abundance of world-class free attractions, including the Art Museum, Zoo, Science Center, Anheuser-Busch Brewery, Grant's Farm, and the Missouri History Museum.

Artsy – Enjoy the art at Laumeier Sculpture Park, the Contemporary Art Museum and the Pulitzer Foundation for the Arts. Music fans will enjoy visiting the historic home of ragtime composer Scott Joplin.

Exciting - nightlife includes six area casinos, colorful local taverns, hundreds of one-of-a-kind restaurants and clubs featuring live blues music.

Famous - the Anheuser-Busch Brewery features the world-famous Budweiser Clydesdales. The heart of the city is the Mississippi River, where you can ride on the Tom Sawyer or Becky Thatcher paddle wheeler.

For more information, visit www.explorestlouis.com.



Notes from the Editor

If you would like to join the SCT or learn more about participating in the 2008 St. Louis meeting, visit the SCT website at www.sctweb.org or contact Mary Burke by phone at 410/433-4722 or e-mail at sctbalt@aol.com.

If you have suggestions for this newsletter, contact SCT Newsletter editor Elizabeth Franks at Fernley & Fernley, Inc. at efranks@fernley.com (phone is 215/564-3484).

