While we greatly appreciate everything our management company, Fernley & Fernley, and their staff have done for us over the years, the Board decided earlier this year that it was time to look for a new management partner.

After an extensive search, we are pleased to announce that, beginning September 1, management of the Society’s operations will be conducted by Executive Administration, Inc (EAI).

EAI is based outside of Chicago and is an accredited management company whose sole focus is on medical professional associations. The company is very successful in retaining its valuable employees, which will help to ensure our staff consistency.

Our new Executive Director is Kevin Bragaw, CPA. Kevin has been an EAI senior-level staff member since 2013. He has more than 18 years’ experience serving in various executive level leadership roles at professional membership organizations, including 8 years with the Chicago Bar Association, 5 years with ISA-CA (a professional IT Association) and 6+ years at EAI overseeing a variety of responsibilities for their health care clients. We look forward to working with Kevin as we continue to grow SCT membership and programs.

An announcement, including our new mailing address and contact information, will be sent to all members in the coming weeks.

We look forward to a bright new future with our new staff.
SCT Members Honored at the 2019 Joint Statistical Meetings

The Joint Statistical Meetings of the American Statistical Association and the Institute of Mathematical Statistics were held in Denver, CO, July 27 through August 1, 2019. We are pleased to announce that three members of the Society for Clinical Trials were honored at the meeting.

The Florence Nightingale David Award was given to Susan Ellenberg, University of Pennsylvania. The award was established in 2001 and is awarded biannually to a female statistician who serves as a role model to other women by her contributions to the profession.

This year the F.N. David lecture was inaugurated and Dr. Ellenberg was doubly honored by giving the first F.N. David lecture.

Susan Ellenberg
University of Pennsylvania

Citation: For her impactful leadership roles at the NIH, FDA, and the University of Pennsylvania developing and evaluating new methodologies and specialized approaches to improve the conduct of clinical trials; for influencing ethical practice and leading development of important regulatory policies, for leadership in setting standards for clinical trial data monitoring committees; for senior statistical leadership for many multicenter clinical research network clinical trials; for distinguished leadership in numerous professional societies and national and international committees addressing major public health challenges; and for serving as an exceptional academic role model for faculty and students.

Scott Evans, the George Washington University, was given a certificate of appreciation as a retiring editor of CHANCE.

Michael Leo LeBlanc, Fred Hutchinson Cancer Research Center, was selected as a Fellow of the American Statistical Association.

By Colin Begg, Editor

The August issue of Clinical Trials features the proceedings of the 11th Annual Conference on Clinical Trials sponsored by the University of Pennsylvania. This year’s conference was focused on estimands, missing data and sensitivity analysis, following the addendum to the International Council for Harmonization guidelines on these topics.

Other topics covered in the August issue include:

- an assessment by Lesley Curtis and colleagues of the challenges posed by changes to relevant policies and/or guidelines during the course of a pragmatic clinical trial
- a report on strategies used to facilitate implementation of a trial to encourage physical activity in an American Indian tribal community in Oklahoma by Jennifer Chadwick and colleagues
- a survey by Nicolas Molinari and colleagues of the impact of adverse publicity about clinical trials on willingness of healthy volunteers to participate in phase I trials.

Finally, we are grateful to Ian Ford who is stepping down after 6 years’ service as a Deputy Editor, and we welcome to our team of Deputy Editors Jonathan Cook from the University of Oxford and Monica Taljaard from the University of Ottawa.

Follow us on twitter @clintrialsj to keep up with the latest from the journal.

Highlights from the August, 2019 Issue
Remembering the Society for Clinical Trials
40th Annual Meeting, May 19-22, 2019 New Orleans, LA

Letitia Perdue
SCT Program Chair 2019 announces the winners of the poster contest.

Ted Karrison, SCT Past-President talks about Paul Meier, his mentor, at the 40th Anniversary Plenary Session on the origins of SCT.

Poster sessions were held Monday and Tuesday.

Libby Wright speaks about her father Thomas Chalmers, a founder of the Society, at the 40th Anniversary Plenary Session.

Dean Fergusson, SCT President 2019-2020 shares his vision of the Society at the Tuesday business luncheon.

Meeting attendees at the Monday Roundtable Luncheon.

Attendees gather for the Monday luncheon.

Celebrating the 40th Anniversary at the Monday night dance party.
There is still time for SCT members to register for the 2019 International Clinical Trials Methodology Conference (ICTMC), October 6-9 at the Hilton Metropole in Brighton, UK at special SCT-only discounted rates!

The 2019 conference will take place in the heart of one of the UK's most vibrant and iconic seaside resorts, Brighton, located on the south coast of England. Brighton has attractions for all; including its world-famous Victorian pier, the grand the Neo-Oriental Royal Pavilion and the 450-foot i360 observation tower, which delivers breathtaking 360 degree views.

The conference facility is the modern Brighton Hilton Metropole, providing the ideal centre to accommodate over 700 colleagues working in trials and trial methodology. A diverse programme will be prepared by the Scientific Committee and Education Committee, which promises to make this a highly rewarding and enjoyable meeting for all.

Brighton is 60 miles south of London on the south coast.

By plane: London Gatwick, the second busiest airport in Europe after London Heathrow, is halfway between London and Brighton.

It is directly connected to London by frequent trains.

**Special SCT Discount Rate Codes:**

- Full Registration **SCT3007** (£375)
- Student Registration **SCTST3007** (£225)

**REGISTER TODAY!**
We are delighted to announce the Scientific Programme for the 5th International Clinical Trials Methodology Conference is now live. To access the programme click on the button below. Please note that this is subject to change.

**VIEW PROGRAMME**

### Pre & Post Conference Educational Workshops

The Educational Workshops are proving extremely popular, to ensure you don't miss out, book now!

<table>
<thead>
<tr>
<th>Sunday 6th October – 09:00 – 13:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Conference Workshop 1.1</td>
</tr>
<tr>
<td>Using Studies Within A Trial (SWATs) to increase the evidence-base for trial process decisions: how to select, design and run them</td>
</tr>
<tr>
<td>Pre-Conference Workshop 1.2</td>
</tr>
<tr>
<td>Design and analysis of clinical trials in the era of precision medicine</td>
</tr>
<tr>
<td>Pre-Conference Workshop 1.3</td>
</tr>
<tr>
<td>Beyond the CONSORT extension for pilot trials: guideline, planning, abstracts and protocols</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sunday 6th October 14:00 – 18:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Conference Workshop 2.1</td>
</tr>
<tr>
<td>Missing data in randomised trials: concepts and design</td>
</tr>
<tr>
<td>Pre-Conference Workshop 2.2</td>
</tr>
<tr>
<td>Strategies for optimising recruitment to challenging randomised controlled trials: the QuinteT approach</td>
</tr>
<tr>
<td>Pre-Conference Workshop 2.3</td>
</tr>
<tr>
<td>Finding and critically appraising a core outcome set (COS) for your trial</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wednesday 9th October – 14:00 – 17:30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Conference Workshop 1.1</td>
</tr>
<tr>
<td>Close Out and Archiving - a CTU guided workshop and discussion session on processes and procedures to conclude a trial</td>
</tr>
<tr>
<td>Post-Conference Workshop 1.2</td>
</tr>
<tr>
<td>Practical Implementation of Bayesian Adaptive Designs for Single-arm, Randomised, Basket and Platform Phase II Trials, with real-world case studies</td>
</tr>
<tr>
<td>Post-Conference Workshop 1.3</td>
</tr>
<tr>
<td>A hands-on introduction to health economics analysis plans (HEAPs)</td>
</tr>
</tbody>
</table>

For further information on the content and presenters of the workshops please [click here](#).

If you have previously registered for the ICTMC 2019 and you wish to register for the Educational Workshops please email ictmc@inconference.org.uk to register.
Recently Posted Guidance Documents and Statements

- 7/22/2019 - Postmarketing Safety Reporting for Combination Products: Guidance for Industry and FDA Staff
- 7/31/2019 E8(R1) GENERAL CONSIDERATIONS FOR CLINICAL STUDIES

FDA issues draft guidance regarding clinical trial design for newborns

Today, the U.S. Food and Drug Administration issued the draft guidance, General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products. The neonatal period is defined as the day of birth plus 27 days for full-term infants and as the day of birth through the expected date of delivery plus 27 days for preterm infants. The draft guidance provides the FDA’s current thinking on clinical pharmacology considerations for neonatal studies for drugs and biological products. It discusses neonatal subgroup classification, dose selection and study design and analysis considerations for the conduct of neonatal clinical pharmacology studies.

FDA & European Medicines Agency collaborate on drug quality and manufacturing data to improve patient access to medically necessary medications

The FDA and the European Medicines Agency (EMA) are publishing the discussion and main conclusions from a workshop held on November 26, 2018, at the EMA headquarters in London, supporting quality development for the FDA’s Breakthrough Therapy Designation and EMA’s Priority Medicines (PRIME) programs for patients with unmet medical needs. The workshop between regulators and industry discussed quality challenges and scientific and regulatory approaches for facilitating development and preparation of robust quality data packages, to enable timely access to medicines for patients while keeping in mind the importance of drug safety and quality and maintaining current standards of approval.
Linking ORCID Identifiers to eRA Profiles to Streamline Application Processes and to Enhance Tracking of Career Outcomes

By Mike Lauer

Enter once, reuse often. That’s the mantra of Open Researcher and Contributor Identification (ORCID), a non-profit organization that promotes the use of its unique digital identifier to connect researchers with their science contributions over time and across changes of name, location and institutional affiliation. With this in mind, in fiscal year 2020, NIH will begin requiring individuals supported by training, fellowship, career development, and other research education awards to have an ORCID iD linked to their personal electronic Research Administration (eRA) account.

Continuing to Work with the Community on Registration and Results Reporting for Basic Experimental Studies involving Humans

By Carrie Wolinetz, Michael Lauer, and William Riley

Basic research involving humans that seeks to understand the fundamental aspects of phenomena also may meet the NIH-definition of a clinical trial. We refer to these studies as BESH – Basic Experimental Studies involving Humans (see our previous blog). Since this type of research meets the NIH definition However, some researchers have faced challenges in fitting these studies into the data fields for submission in ClinicalTrials.gov. The NIH has determined that more time is needed to address these challenges. Today, NIH published a Guide Notice (NOT-OD-19-126) announcing the extension of delayed enforcement of registering and results reporting of BESH on ClinicalTrials.gov through September 24, 2021.

Achieving Gender Equity at Conferences

By Mike Lauer

Inviting women to speak at conferences matters for many reasons – it’s a matter of fairness; it gives eminently qualified women a level playing field; it is just the right thing to do. In essence, it’s about changing the fundamental culture of the biomedical research enterprise to allow full participation from people of all backgrounds. In that vein, I’d like to remind you that if you are applying for an R13 conference grant from NIH, please be sure to read the requirements in the Funding Opportunity Announcement, where meeting diversity is a long-standing expectation.

New Resources

New “All About Grants” Podcast on NIH’s Anti-Sexual Harassment Policies for Awardees

Sexual harassment is a serious and long-standing issue within the biomedical research enterprise, and NIH is striving to be part of the solution. On this episode of the “All About Grants” podcast, we sit down with Dr. Jodi Black, Deputy Director for the NIH’s Office of Extramural Research, to discuss what institutions, investigators, and others in the research community should know about NIH’s policies and expectations for assuring a safe and harassment-free work environment.
THANK YOU TO OUR CORPORATE SPONSORS!

Platinum Sponsor

Gold Sponsor

MERCK

Silver Sponsors

AbbVie
Amgen
Axio
Berry Consultants
Complar
Greenphire
JCHR
Statistics Collaborative
Servier

Bronze Sponsors

Emmes
Clinical Medicine

An Open Access Journal by MDPI
Save the Dates—Upcoming SCT Annual Meetings

41st Annual Meeting May 17-20, 2020
Baltimore, Maryland USA

42nd Annual Meeting May 16-19, 2021
Chicago, Illinois USA

Executive Committee
Dean Fergusson (President)
Susan Halabi (President-Elect)
Sumithra Mandrekar (Past-President)
Domenic Reda (Secretary)
Li Chen (Treasurer)

Committee Chairs
Program: Abigail Shoben
Program: Jonathan Cook (Co-Chair)
Education: Yves Rosenberg
Communications: Liz Garrett-Meyer
Fellows: Mithat Gönen
Membership: Jody Ciolino and Dixie Ecklund
Nominating: Lehana Thabane
Student Scholarship: Wendy Seiferheld and Sharon Yeatts

Board of Directors
James Dignam (2017-2021)
Emily V. Dressler (2018-2022)
Alexia Iasonos (2019-2023)
Roger J. Lewis (2016-2020)
Robert Lindblad (2019-2023)
Leslie Ain McClure (2016-2020)
Will Meurer (2017-2021)
Pamela Tenaerts (2018-2022)
Elizabeth Thom (2017-2021)

Newsletter Editor—Domenic Reda
Webmaster—John Hepler