Hello everyone,

I would like to wish everyone a very happy and healthy 2019 on behalf of SCT. Hope you had a relaxing time over the holidays connecting with friends and family.

The 40th Annual Meeting is approaching quickly, and I am very excited to let you know that the SCT committee chairs have been working diligently to plan the meeting events. We are in the midst of finalizing the program, special thanks to our program and education committee members for their hard work over the holidays in reviewing the submissions. The review of the submissions for the trial of the year, student scholarship awards and other contributed sessions are ongoing. Stay tuned for information on some special sessions that are being planned to commemorate the 40th year of the meeting. We will have Drs. Fleming and Bertagnolli giving the plenary lectures at this meeting. We also plan to have a social event with a DJ and a dance floor, so tune up your dance moves and bring your dancing shoes along!

Please look for more information in this newsletter regarding the Annual Meeting, venue, registration, etc., and plan your travels early to be there at the 40th Annual Meeting of the SCT at New Orleans from May 19 - 22, 2019. In this issue of the newsletter, we also include a spotlight on the Jaeb Center for Health Research, in addition to a number of other important announcements.

Happy reading, and once again warm wishes for a wonderful 2019!

From: Sumithra J. Mandrekar, Ph.D.
Registration is Now Open!

40th Annual Meeting of the Society for Clinical Trials
May 19 - May 22, 2019
New Orleans, LA

SCT's 40th Annual Meeting:
"Clinical Trials: A Catalyst for Societal Advancement through Innovation"

It's time to register for the Annual Meeting of the Society for Clinical Trials! The meeting will once again offer a multidisciplinary program with broad participation. The event brings together the clinical trials community from academia, the pharmaceutical and device industries, government agencies, medical groups and centers and clinical research entities.

Highlights include:

- Plenary sessions, simultaneous workshops invited presentations, contributed presentations and posters
- Pre-meeting workshop courses by leaders in the field
- Annual student scholarship competition
- Exhibitors showcasing publications, technology and other resources for clinical trials
- Discussions of timely issues and research experiences among colleagues in the field
- Presentation of the 2018 Trial of the Year Award
- Presentation of the SCT Class of 2019 Fellows

New to the 2019 SCT Program!
The SCT Meeting will be hosting round-table sessions focused on small group discussions and opportunities to be an involved SCT member during the Monday luncheon. Registration is required (at no cost) so please look for it on the meeting registration form.

Refer a Colleague to SCT!
In an effort to promote SCT membership within the current members' networks, the Membership Committee initiated a lottery for this year's annual meeting. Please consider referring a colleague or friend, especially in a field different from your own, who you think would benefit from SCT involvement. The meeting registration form will have a section for your referral to enter your name into the lottery. If you are selected, you will receive a gift card! The more referrals you have, the higher your chances of winning.

Learn more about SCT's 40th Annual Meeting
Hotel Accommodations Now Available

Sheraton New Orleans Hotel
New Orleans, LA

SCT standard room rate starts at $239 per night

Government rates available (with valid ID) starting at $150 per night

LEARN MORE
I started the JAEB Center for Health Research (JAEB) in 1993. My story prior to that is that I was trained as an ophthalmologist and joined the faculty of the University of Michigan as Director of the Neuro-ophthalmology Service in 1982, subsequently moving to a similar position at the University of South Florida (USF) in 1986. Starting in 1985, as Chairman of the multi-center Optic Neuritis Treatment Trial (ONTT) funded by the National Eye Institute (NEI), I had the good fortune to have our Coordinating Center at the Biostatistics Center at George Washington University under the direction of Paddy Cleary and John Lachin. This was a life changer for me professionally as I learned an incredible amount from them and decided that ultimately, I wanted to do what they did—run a coordinating center for multi-center trials. So, while on the faculty at USF, I received a Physician Scientist Award from NIH (predated the current K awards) and used it to obtain a PhD in epidemiology at the USF College of Public Health.

At about the time I completed the PhD program, I started a coordinating center at USF; and when the ONTT ended and an epidemiologic study of the relationship of optic neuritis to multiple sclerosis began (the Longitudinal Optic Neuritis Study-LONS, which continued for 15 more years), the coordinating center was moved from George Washington to USF. I soon became frustrated by the bureaucracy of trying to build a coordinating center within the administrative constraints of a university, particularly a state institution, and decided to set up an independent nonprofit entity near the USF campus in 1993.

The JAEB Center is celebrating its 25th anniversary this year. So, it is fitting to detail our history. Through the course of these 25 years, our main focus has been serving as a coordinating center for multi-center investigator-initiated clinical trials, mostly NIH or foundation-funded. In view of my background as an ophthalmologist, one of our major areas of focus has been in eye diseases. Starting with LONS, JAEB became the coordinating center for the Herpetic Eye Disease Study (HEDS) funded by the NEI, which conducted several RCTs and an epidemiologic risk factor study in the 1990s. HEDS had 74 clinical sites,
including both university-based and community-based sites. Thereafter, incorporating community-based sites into clinical trials became a major focus of many of our projects.

In 1997, I with two pediatric ophthalmologists Michael Repka at Johns Hopkins and Jonathan Holmes at the Mayo Clinic formed a network of pediatric eye care providers to conduct studies in eye disorders affecting children, called the Pediatric Eye Disease Investigator Group (PEDIG). PEDIG, which is funded by the NEI, has been an open network that allows participation by any site that has the requisite qualifications. The network includes both ophthalmologists and optometrists, and the collaboration of the two disciplines has been one of the rewarding aspects of PEDIG. Since its inception, 234 sites and 908 investigators have participated in PEDIG (currently 123 sites active in at least one protocol), with about 40% community-based and 60% university-based. Over the last 20 years, PEDIG has conducted 47 protocols, 10 of which are currently in progress.

We followed the same model of an open-network with both academic and private practice sites in the Diabetic Retinopathy Clinical Research Network (DRCRnet), for which we were awarded the coordinating center grant in response to a Request for Applications (RFA) in 2001. In collaboration with the two other RFA awardees, Lloyd Paul Aiello at the Joslin Diabetes Center at Harvard who was the inaugural network chair, and Matthew (Dinny) Davis who headed the Fundus Photograph Reading Center at the University of Wisconsin, the network was established. Since its inception, 352 sites and 1307 investigators have participated in DRCRnet (currently 153 active sites in at least one protocol), with about 65% community-based and 35% university-based. Over the last 17 years, DRCRnet has conducted 31 protocols, 11 of which are currently in progress. This year, 2018, the network is expanding beyond diabetic retinopathy to all retinal diseases.

JAEB also has been the coordinating center for two NEI-funded multi-center cornea disease clinical trials: the Cornea Donor Study (1999-2013) and the Cornea Preservation Time Study (2012-2017, for which coordinating center functions were shared with Case Western Reserve University), and since 2016 has coordinated a rare retinal disease international consortium funded by the Foundation Fighting Blindness. Recently, returning to my roots in neuro-ophthalmology, JAEB became the coordinating center for the NEI-funded SIGHT study, a randomized trial comparing medical and surgical treatments for idiopathic intracranial hypertension.

That is only half of JAEB’s history. The other half involves studies in diabetes, primarily type 1 diabetes (T1D). JAEB’s involvement in diabetes research emanating from one of my three children developing T1D at age 12 in 1992. After a few years of daily learning about T1D at home, I decided to dedicate a portion of my time and our center’s resources to diabetes studies. This decision came at a fortunate time in that Congress appropriated special funding for T1D research to the NIH, which put out several RFAs for coordinating centers. We were selected to be the coordinating center for the Diabetes Research in Children Network (DirecNet) in 2001, which over the next 12 years conducted numerous clinical trials and epidemiologic studies in children with T1D. Our DirecNet involvement led to the development of a close working relationship with the Juvenile Diabetes Research Foundation (now, JDRF), starting with JDRF funding to JAEB for a landmark continuous glucose monitoring clinical trial in 2007 and establishment at JAEB of an artificial pancreas studies coordinating center, which has become a major focus of JAEB’s diabetes studies. Currently, JAEB is coordinating four NIDDK-funded artificial pancreas projects as well as JDRF and industry funded projects.
In 2010, the Helmsley Charitable Trust became a major funder of T1D research and provided support to JAEB to build a network of 80 adult and pediatric diabetes centers. This project has included development of a longitudinal registry of about 35,000 adults and children with T1D and the conduct of 9 clinical trials and 16 other studies, utilizing the registry participants as a potential source for study participants. The registry datasets have been made public as a resource for researchers internationally. Mixed in with these T1D studies have been a few type 2 diabetes studies.

Paddy Cleary introduced me to the Society for Clinical Trials in 1985. I have been a strong supporter since then, serving on a number of committees including the Board of Directors from 2000-2004 and being selected to be a Fellow of the Society in 2010. JAEB statisticians and epidemiologists have been regular attendees and presenters at the annual meeting. Two of our staff to recognize for their contributions to SCT are Pamela Moke and Michele Melia. Pam was one of three original employees at the Jaeb Center in 1993 and spent 23 years here until her retirement in 2016, filling the role of a chief information officer for most of her tenure. Michelia Melia joined JAEB in 2004 as a senior statistician and has been active in SCT, having served two stints on the Board of Directors as well as being a member of many committees and being selected to be an SCT Fellow in 2015.

Over the years, I and our staff, currently numbering 130, have had the good fortune to work with amazing groups of investigators and NIH and foundation program officers whose collaborations with us have been rewarding and impactful.

Finally, people always ask where the name JAEB comes from. It is not a philanthropic family but rather the initials of my children in order of age-Jody, Andy, Eric (Beck).
University of Pennsylvania's
April 17, 2019

12th Annual UPENN Conference
on
Statistical Issues in Clinical Trials
ELECTRONIC HEALTH RECORDS (EHR) IN RANDOMIZED CLINICAL TRIALS
CHALLENGES AND OPPORTUNITIES

Registration is now open

Click for more details
Excerpts from

Open Mike

Resources for Rigorous Research
By Mike Lauer
Advancing public health depends on science being empirical, transparent, and rigorous. As yet another step towards fostering rigorous science, we have revamped the Rigor and Reproducibility webpage to highlight and include more resources you might find helpful. Since sketching out our plan last summer with the Advisory Council to the NIH Director, the webpage now reflects policy updates and explores new resources, all in a simple and easy to read manner. Continue reading →

Top Stories

FY 2019 Fiscal Policies for Grant Awards: Funding Levels, Salary Limits, and Stipend Levels
NIH issued guidance for NIH Fiscal Operations for FY 2019 including the following new policies on funding levels, salary limits, and stipend levels. Continue reading →

Always Check Your FOA for New Related Notices 30 Days Before Submission
You found a funding opportunity announcement (FOA) that fits your research, you’ve read it carefully, and have been working for months perfecting your application. Don’t forget to return to the FOA within 30 days of the due date to check for any new related notices which could impact your submission. Continue reading →

Reminder of Policy Changes
For your convenience, here is a roundup of recently announced changes impacting grant application submission for due dates on or after January 25, 2019. Continue reading →

NIH Implementation of the Final Rule on the Federal Policy for the Protection of Human Subjects (Common Rule)
NIH has issued initial guidance on the implementation of the Revised Common Rule NOT-OD-19-050. The effective date for the amended regulation is January 21, 2019. It applies to studies initiated on or after this date, and ongoing studies that voluntarily transitioned to the Revised Common Rule, including those that implemented the three burden-reducing provisions during the delay period (July 19, 2018 through January 20, 2019). Continue reading →

Resources

New Resources Available for Basic Experimental Studies with Humans (BESH) Funding Opportunities
In November, NIH announced the publication of new funding opportunities specifically for Basic Experimental Studies Involving Humans (BESH). Need help determining if your research fits within the scope of a BESH funding opportunity announcement (FOA)? Check out these new resources. Continue reading →

You Ask, We Answer

Can My Application be Considered a Resubmission Even if I am Not Re-Submitting to the Same FOA?
It depends on whether the FOAs are Program Announcements (PA, PAR, PAS or Parent) or Requests for Applications (RFA). Continue reading →

Is My Ancillary Study Considered a Clinical Trial?
It depends. Yes; if the ancillary study adds an additional prospectively assigned intervention to patients or a sub-population of patients within the larger clinical trial and all elements of the NIH clinical trial definition are met. No; if the ancillary study is only adding additional measures to an existing clinical trial. Continue reading →
Excerpts from

**PROJECT UPDATES**

**CTTI to Support NIH Workgroup in Developing Evaluation Plan for Single IRB Policy**

The NIH has selected CTTI to support a workgroup that will develop a comprehensive plan for assessing the NIH’s new single institutional review board (sIRB) policy. The policy, which became effective in January, requires U.S. sites participating in nonexempt multicenter human subjects research funded by the NIH to use a sIRB for ethical review, with the goal of improving the quality and efficiency of clinical research. “For nearly a decade, CTTI has championed the adoption of sIRBs for multicenter clinical trials,” said CTTI Executive Director Pamela Tenaerts. “We are excited to use our expertise to craft an evaluation plan for the NIH policy, and to design standard evaluation methods that can be used by academic organizations, research sponsors, and others who are interested in implementing sIRBs.” [Read more about this news and learn more about CTTI’s ongoing sIRB work.]

**CLINICAL TRIALS NEWS & ANNOUNCEMENTS**

**CTTI Work Cited in FDA’s New Framework for Use of RWE in Regulatory Decisions**

CTTI’s work on [registry trials](https://www.ctti-clinicaltrials.org/registries) and [real-world evidence](https://www.ctti-clinicaltrials.org/real-world-evidence) was referenced in the FDA’s recently announced [2019 strategic framework](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm634686.htm) for advancing opportunities to use electronic tools to gather health-related data. In a [statement](https://www.fda.gov/news-events/press-announcements/fda-commissioner-statement-on-strategic-framework-for-electronic-data-usage), FDA Commissioner Scott Gottlieb asserted that leveraging real-world data (RWD) collected during the routine care of patients to improve regulatory decisions is a key strategic priority for the FDA. RWD gathered from a variety of sources—including electronic health records (EHR), medical claims, and registries—have the potential to strengthen regulatory oversight and advance the development of novel therapeutic products.

**FDA Issues Draft Guidance for Industry on Biomarker Qualification**

The FDA recently published a [draft guidance](https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm630139.htm) for industry on determining the type and level of evidence sufficient to support qualification of a biomarker for use in drug development. The guidance is intended to promote development of biomarkers and their broader application in drug development by providing a clear, predictable, and specific framework for the evidence needed to support regulatory acceptance of a biomarker for a specific use. For more information on identifying, selecting, and developing endpoints derived from mobile technologies, see CTTI’s [MCT Novel Endpoints recommendations](https://www.ctti-clinicaltrials.org/mct-novel-endpoints).

**NIH/NINDS Clinical Trials Methodology Course Accepting Applications for 2019**
The Clinical Trials Methodology Course (CTMC), supported by the National Institutes of Health (NIH) and the National Institute of Neurological Disorders and Stroke (NINDS), is accepting applications for 2019. The application deadline is Feb. 28, 2019, at midnight PT. The purpose of the CTMC is to help investigators develop scientifically rigorous, yet practical clinical trial protocols. Qualified applicants from clinical disciplines focused on neurological disease or injury, along with biostatisticians working on projects with clinical neuroscience researchers, should apply. The CTMC includes both distance learning activities and a required residential course, which will be held July 22-25, 2019, in Iowa City, Iowa. Funding for travel (within the U.S.) and accommodations will be provided for participants.
Excerpts from the December 2018 edition

This issue:

Trials Methodology Research Partnership

HTMR Network Autumn 2018 Webinar uploads

COMET VII meeting

Course: Introduction to RCTs June 2019

Short Courses in statistics: Lancaster University

Funding News: Trials Methodology Research Partnership

As 2018 draws to close, the MRC HTMR Network is delighted to announce that the Trials Methodology Research Partnership funding application, which was submitted to the MRC-NIHR Methodology Research Programme in June, has been successful.
The Trials Methodology Research Partnership (TMRP) will bring together a number of networks, institutions and partners working in trials and trials methodology research.

At present, the partner networks who will join the five Hubs within the MRC HTMR Network include the Global Health Network (TGHN), Health Research Board Trials Methodology Research Network (HRB-TMRN), Health Data Research UK, the UKCRC Registered CTU Network and the UK Trial Managers’ Network (UK TMN). In addition, groups from 21 universities are collaborating to offer doctoral training in trials methodology research to a new cohort of students (Aberdeen, Bangor, Birmingham, Cardiff, Edinburgh, Exeter, Glasgow, King’s, Lancaster, Leeds, Liverpool, LSTM, Manchester, MRC BSU, MRC CTU, Newcastle, Nottingham, Oxford, QMUL, Sheffield, York).

Professor Paula Williamson, current HTMR Network Chair and Lead for the new partnership, commented “Our vision is to foster an environment which attracts the very best trials methodologists, both as staff, students and collaborators, working in areas of high priority and with key stakeholder groups to exert influence and achieve impact. Our overall aim being to improve patient care by improving the way in which the healthcare evidence base is developed.”

The TMRP offers an opportunity to build on the achievements of the MRC HTMR Network while exploring new collaborations and avenues to make continued progress in advancing trial methodology, developing capacity and further reducing research waste. The Partnership will be launched late spring 2019.
The Autumn 2018 HTMR Network Trial Conduct Webinars are now available to view. Please see the HTMR Website:

http://www.methodologyhubs.mrc.ac.uk/resources/webinars/

**Making more of your study by using SWATs**
Lucy Culliford, Research fellow, Bristol University

**Challenges of conducting a pre-hospital emergency care trial: Experiences from the PARAMEDIC2 trial**
Charlotte Scomparin, Warwick CTU, University of Warwick

**Mapping Recruitment Research Literature: What’s next?**
Anna Kearney, University of Liverpool

If would you be interested in presenting a webinar? Perhaps you would like to re-share a conference paper or publicise a publication or study? Email us.

**COMET VII meeting: November 2018**

On the 15th and 16th November 2018, the Core Outcome Measures in Effectiveness Trials (COMET) Initiative held its seventh international meeting. One-hundred and fifteen participants gathered from around the world, coming from five continents and 18 countries.

COMET was awarded an MRC HTMR Impact Award to support the attendance of, and participation of, up to five researchers from low and middle-income countries (LMIC) at COMET VII. Four participants successfully joined COMET VII, which included researchers from Brazil, India and two different regions of Africa.

COMET VII consisted of a day and a half of plenary talks, contributed presentations, posters and workshops. Speakers’ presentations will be available in due course at http://www.comet-initiative.org/events/pastcomet.

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MRC HTMR Network 7th Annual meeting 25th September 2018

Over 80 hub members gathered together at the Wellcome Collection, London, on the 25th September.

The day was filled with a varied programme of talks including examples of novel trials, statistics, trial design, trial conduct and patient perspectives.

A selection of presentation slides from the day are available here.

Introduction to Randomised Controlled Trials: June 2019

Introduction to Randomised Controlled Trials

Bristol University. 10-14th June 2019

Aim: To provide an understanding of the essentials of designing, conducting and analysing randomised controlled trials (RCTs). The course examines RCTs evaluating health and public health interventions in primary, secondary and community settings with individual and cluster randomised designs.

It is designed for health care researchers, trial managers and coordinators, clinicians, public health researchers and specialists looking to understand RCTs. and covers the following topics:

- Design of trials
- Randomisation
- Sample size
- Feasibility and pilot studies
- Trial planning, resourcing and working with the NHS
- Process evaluation for patient experience
- Patient and Public Involvement
- Optimising trial recruitment
- Trial conduct
- Protocol adherence and missing data
- Cluster and public health trials, including in schools
- Outcome assessment and Patient Reported Outcome Measures
- Health economics
• Primary and secondary trial analyses
• Experience of being a Chief Investigator
• Clinical Trials Unit support for trialists

Course tutors
Dr Athene Lane, Professor Chris Metcalfe (course organisers) and others.

Click here for further details and how to apply

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**Short Courses in statistics: Lancaster University 2019**

For Statisticians, Scientists, Social Scientists, and Health Researchers

- Introduction to Statistical Learning (Data Mining I) – 21st & 22nd January
- Next steps in Statistical Learning (Data mining II) – 4th & 5th February
- Pharmacological Modelling - 11th to 14th February
- Multi-level Models - 18th & 19th February
- Survival and Event History Analysis course - 25th to 28th February

Statistical Genetics and Genomics – over 3 weeks in Feb and March 2019

- Methods for Missing Data – 4th & 5th March
- Bayesian Methods – 28th Feb to 1st March
- Adaptive Methods in Clinical Research - 11th to 14th March
- Structural Equation Modelling - 18th & 19th March
- Designing Phase I Dose Escalation Studies - 10th & 11th June

To book a place or for more information please see here.

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*Visit the Network's Training Resource for more training events*
Find out about the MRC HTMR Network, training, workshops, publications and more on our website:

www.methodologyhubs.mrc.ac.uk

Keep in touch

Online: www.methodologyhubs.mrc.ac.uk

By email: enquiries@methodologyhubs.mrc.ac.uk

Follow us at: @MRCHTMRNetwork

The HTMR Network is not responsible for the content of any external websites. Deadlines are correct at time of circulation. It is the applicants responsibility to ensure the correct submission deadline for any funding scheme or for conference registration.
Save the Dates

Upcoming SCT Annual Meetings

Baltimore - May 17 - 20, 2020

Chicago - May 16 - 19, 2021