Message from the President

I hope everyone had a relaxing summer and getting ready for the back to school and back to work craziness! Well, summer flew by for me and we are already starting to feel the cool fall temperatures in Rochester, MN!

New this year, we put together an SCT Annual Meeting Planning Committee to think about and make suggestions for the 2019 Annual Meeting.

One of the first tasks was to discuss a possible theme for the 2019 meetings, as well as how to structure the program so it reflects a more comprehensive meeting with a wide range of topics on clinical trials conduct and methodology.

The other main goal of this committee was to increase the communication across the program, education, and trial of the year committees, and to integrate industry speakers and topics, leadership development, and clinician focused sessions. The committee met every 2 weeks starting in early July, and brainstormed on various initiatives for the meeting. I will provide a few snippets below, but keep reading the newsletters and browse the meeting website for regular updates.

The theme for the 2019 meetings is: **Clinical Trials: A Catalyst for Societal Advancement through Innovation.**

The program and education committee chairs have integrated this theme into the call for proposals for invited and contributed sessions, posters, pre-meeting workshops and in-conference tutorials. New in 2019, we plan to organize a few roundtable sessions to give our new members an opportunity to learn about our society, and our current members a glimpse into the many opportunities for leadership and involvement with the society. Also, please polish up your dancing skills as we are planning on a dance party in New Orleans 😊

Members of the 2019 meeting planning committee included: Wendy Parulekar, Scott Evans, Letitia Perdue, Lynda Constable, Valerie Durkalski-Mauldin, Li Chen, Tia Diggs, Mary Keller, Jamie Cohen, and myself.
The call for submissions is now open, and we look forward to receiving all your submissions! Please visit the meeting website at [http://sctweb.org/meeting](http://sctweb.org/meeting) for all the details.
Call for Content for SCT 40th Annual Meeting
May 19 - 22, 2019 - New Orleans, LA, USA

Important Deadline
Invited Session Abstracts Submit by November 1, 2018
Contributed Paper & Education Proposals - Submit by November 30, 2018

The Society for Clinical Trials is now accepting submissions for content for its 40th Annual Meeting, to be held May 19-22, 2019 at the Sheraton New Orleans Hotel in the heart of the city. The theme for this year's meeting is "Clinical Trials: A Catalyst for Societal Advancement through Innovation."

How to Submit

This year, for all submission types (contributed, invited and education sessions), you will first be required to fill in some basic information including the primary contact and contact information; submission type; and answer a few questions about your abstract including whether the abstract applies to the theme, identify three categories (http://www.sctweb.org/docs/Keyword_Categories.docx), and identify your target audience.

After you have submitted this, you will be directed to a page specific for the type of submission (invited, contributed or educational). Information entered on this second page can be edited until the system is officially closed.
For all submissions, you'll need to include the following information:

- Primary contact for the proposal (with affiliation and email address)
- Whether the proposal is tied to the overall theme (including a brief description)
- Category
- Target Audience

All submissions must be made via the SCT website page for the 40th Annual Meeting.

Click here

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*Invited Session Proposals*

An Invited Session typically brings together a set of speakers and discussants to present the latest results of important and emerging issues in an area of clinical trials research.

Formats vary for invited sessions; however, all are 90 minutes in length and have a session chair. The sessions typically include 3-5 participants; including the chair, with two of the most successful formats being 2-3 speakers with a discussant or a panel discussion of 3-4 panelists.

Proposals should be submitted by November 1, 2018.

Your proposal should contain the following information:

- Title
- Speakers (with affiliation and e-mail addresses for each)
- Session organizer (with affiliation and e-mail address) (please add in additional contributors space)
- Session chair (with affiliation and e-mail address) (please add in additional contributors space)
- Proposed session type (invited talks, panel, other)
- Written description of session, including focus, content, timeliness, appeal, and relevance to the theme, as well as specific titles for each speaker's talk (if applicable)

To submit abstracts: Click here

If you have questions about part of your proposal or want some feedback prior to finalizing your submission, please consider emailing us at program@sctweb.org.
**Contributed Papers and Posters**

Contributed abstracts on topics of interest to the diverse membership of the Society are requested.

To submit:

- Specify if the abstract should be considered for either a paper or poster session (to be decided by the program committee) or a poster session only.
- Those selected for podium presentation will be grouped with other presentations having a similar theme, but topics within a session may be diverse and not connected to other papers presented in the session.
- Papers are usually allotted 15 to 20 minutes and four to six papers are presented in a session.
- Submitted abstracts may appear in the final program exactly as submitted. Thus, contributed abstracts should be as accurate and specific as possible. Preference will be given to abstracts that report completed investigation, analyses, designs, or methodological work over those that promise to report a work in progress if accepted.

**Proposals should be submitted by November 30, 2018.**

The abstract must contain, in the following order:

- Title in all capital letters with no abbreviations
- Full names of authors without degrees or titles
- Institutional affiliation, city, state or country of first author *(additional contributors or authors can be added in space provided)*
- Text of the abstract (500 word limit)
- Proposals for contributed papers and posters must be submitted by November 30, 2018. Notifications on acceptance for podium or poster presentation will be communicated in February 2019

*Please note: To be certain that your proposals are received and considered, please ONLY submit Contributed Papers and Abstracts by clicking here*

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**Education Workshop Proposals**

The Education Committee invites proposal submissions for consideration for the pre-conference educational workshops and in-conference tutorial sessions for the 40th annual SCT meeting. The theme of this 40th Annual Meeting that will be held in New Orleans from May 19 to May 22, 2018 is "Clinical Trials: A Catalyst for Societal Advancement through Innovation."

Some of the themes we are particularly interested in for this year’s workshops/tutorials meeting will include:
- Clinical trial conduct: recruitment and retention, ethics, study start up/close-out in multi-center trials, international trials, trial evolution over time
- Patient reported outcomes and patient perspectives in clinical/trials decision making
- Trial design and/or analysis: innovations in trial methods and outcomes
- Artificial intelligence and ‘data deluge’
- Data sharing: Preparing, submitting and accessing trial data from data sharing platforms
- The working of Data Monitoring Committees

Pre-conference educational workshops will be offered on Sunday, May 19th, 2019. These are typically short courses on topical methods or issues related to clinical trials typically lasting around 4 hours. The focus will be on education and training and will include hands-on work and plenty of time for questions and discussion. Please include a bullet point description of how the workshop will be structured (e.g. 10-min presentation followed by 30-mins of small group work with hands-on use of software etc). Pre-conference Workshops are offered at an additional cost to the attendees.

In-conference tutorials will be offered during the main meeting from May 20-22nd, 2019. These are interactive sessions on a method or topic related to clinical trials. Tutorial sessions are not intended to be purely didactic but will have plenty of time for discussion and may include small-group work, hands-on use of tools and software, troubleshooting and ‘ask-the-expert’ time. In-conference tutorial sessions typically last 90 minutes. Please include a bullet point description of how the tutorial will be structured (e.g. 10-min presentation followed by 30-mins of small group work with hands-on use of software etc.).

For all submissions, please include the following information:

- Primary contact (with affiliation and email address)
- Whether the proposal is tied to the overall theme (including a brief description)
- Category
- Target Audience

Submitted proposals will be reviewed and scored by the Education Committee, and a liaison identified for each proposal to work in close collaboration with the proponents to address the comments from the Committee. Proposals addressing similar topics will be encouraged to merge together to form a single proposal.

The submission portal for the pre-conference workshops and in-conference tutorials will open on September 7 2018 and close on November 30 2018. We look forward to receiving your submission for consideration for the 40th SCT annual meeting!

[Click here]
For more information on the SCT Annual Meeting, in New Orleans, LA, USA, including hotel information, visit the [SCT 40th Annual Meeting page](#). Registration opens in January 2019.

In the meantime, spread the word about this "Call for Content" with your colleagues, students and all those interested in the design and dissemination of knowledge about clinical trials.

Sincerely,

**Tisha Perdue**

SCT 2019 Program Chair

**Abby Shoben**

SCT 2019 Program Co-Chair

**Lynda Constable**

SCT 2019 Education Chair

**Yves Rosenberg**

SCT 2019 Education Co-Chair
A Note from the Program Committee
By Tisha Perdue, SCT 2019 Program Chair

The Program Committee is already receiving submissions and is excited about the upcoming theme for the 40th Annual Meeting:

“Clinical Trials: A Catalyst for Societal Advancement through Innovation.”

We have expanded the list of topics that appeared in the original Call for Content, incorporating ideas generated by the survey completed by last year’s attendees. Please consider whether you, or one of your colleagues, would be interested in presenting on one of these for an Invited Session!

- Building Transparency into Clinical Trials
- Harmonization of clinical outcomes
- Adaptive trial designs using apps, interactive software, or electronic data capture
- Evaluating conduct and data quality: risk-based vs on-site monitoring; creating data quality reports; how to entrust data pulled from EHR
- Lessons learned with Central IRBs
- SMART (Sequential Multiple Assignment Randomized Trials)
- Best practices for Recruitment & Retention
- Clinical trial conduct: recruitment and retention, ethics, study start up/close-out in multi-center trials, trial evolution over time
- Patient reported outcomes and patient perspectives in clinical/trials decision making
- Trial design: innovations in trial methods and outcomes
- Artificial intelligence and data deluge
- Data sharing: Preparing, submitting and accessing trial data from data sharing platforms
- The working of Data Monitoring Committees
The Joint Statistical Meetings (JSM) were held July 28 through August 2, 2018 at the Vancouver Convention Center in Vancouver, Canada. We are pleased to share that three members of the Society for Clinical Trials were selected as Fellows of the American Statistical Association.

Please join us in congratulating:

- Ying Qing Chen, Fred Hutchinson Cancer Center
- Roger J. Lewis, Harbor-UCLA Medical Center
- Leslie Ain McClure, Drexel University

If you have recently received an honor or know of another SCT member who has received an honor, please let us know (sct@fernley.com) so we can highlight the accomplishments of our members.
Dear SCT Members,

We are soliciting nominees for President-elect for 2019-2020 and members of the Board of Directors (two) for 2019-2023.

Please let us know of anyone that you would recommend as a possible candidate. If you, yourself, are interested in serving the Society in either of these roles, please do not hesitate to put your name forward.

The Nominating Committee will consider all proposed candidates and, from the list of willing nominees, select a slate of candidates for the ballot. This year, the Nominating Committee consists of Sumithra Mandrekar (President), Dean Fergusson (President-elect), Jim Dignam (Board member), Will Meurer (Board member), Jenny Donovan (Member at large) and Lehana Thabane (Member at large appointed as Chair by President).

To qualify as a candidate, the person should be:

- A member of the Society in good standing by having been an SCT member for five years or longer consecutively and preferably one who is or has been an active participant in SCT activities and/or committees.

- Someone who is well respected in their area of clinical trial activities, whether it be in information technology, patient care, statistics, project management, regulatory affairs, epidemiology, laboratory sciences, or any of the other disciplines that are important for the planning, conduct, analysis, interpretation and reporting of clinical trials.

Please contact Lehana Thabane, Chair of the Nominating Committee (thabanl@mcmaster.ca) with your nominations by COB on Monday, December 17, 2018.
Save the Date for October's Webinars
Two new webinars have been scheduled for October, 2018

October 5, 2018 10:00 AM EDT

*Ethics and Design of Cluster Randomization in Public Health and Medicine*

**Presenters:** Monica Taljaard, PhD and Charles Weijer MD, PhD

**Description:** Cluster randomization is increasingly being used to advance the pragmatic trials agenda. Cluster randomization can take the form of a simple parallel arm design, but cluster cross-over and stepped wedge designs are becoming popular as they can reduce the required number of clusters.

[Click here for more information on presenters, topic and to register for this Webinar](#)

October 17, 2018 9:00 AM EDT

*Studies Within A Trial (SWATs): how they can help to improve the efficiency of trial recruitment and retention*

**Presenter:** Professor Shaun Treweek

**Description:** Trials are important; very often they are also inefficient. Trial Forge (http://trialforge.org) aims to improve trial efficiency by identifying and then filling gaps in trial process evidence. There are plenty of gaps, even for key processes such as recruitment and retention. For example, there is currently high certainty evidence to support just three things trialists could use to improve recruitment in their trial.

[Click here for more information on presenter, topic and to register for this Webinar](#)
Highlights of the October Edition of *Clinical Trials*

By Colin Begg

The October issue of *Clinical Trials* as usual features articles on a range of topics of interest to the Society for Clinical Trials membership. Thomas Mooney and colleagues examine their experiences in setting up a vaccine trial during the West African Ebola epidemic, concluding that research should be closely integrated with public health outbreak response planning. Bobbi Scherer and colleagues report on their experiences in conducting a multi-center trial in the military, highlighting the challenges unique to this setting. Victoria Pemberton and colleagues studied the recruitment success of NHLBI cardiovascular clinical trials, reporting that only 23% met their definition of recruitment success.

Are you Following *Clinical Trials* on Twitter? Please add @ClinTrialsJ to the accounts you follow on Twitter to keep up to date with the latest from the journal. Here's some recent tweets.

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**Clinical Trials** @ClinTrialsJ Sep 12

Of 167 @nih_nhlbi trials analyzed, 26.3% attained 100% recruitment. 24 trials (14.4%) were terminated early and 15 (62.5%) for insufficient recruitment. New policy not helping significantly. [journals.sagepub.com/doi/full/10.1177/1740774518792271](journals.sagepub.com/doi/full/10.1177/1740774518792271)

7:07 AM - 12 Sep 2018

**Clinical Trials** @ClinTrialsJ Sep 12

Quality of life data, reporting, and analysis in randomized cancer clinical trials. From tower of babel to lingua franca. @SCT_ORG [journals.sagepub.com/doi/full/10.1177/1740774518792271](journals.sagepub.com/doi/full/10.1177/1740774518792271)

7:00 AM - 12 Sep 2018
Isotonic designs can be a good alternative to model-assisted methods in dose escalation studies, say @nawages and Mark Conaway in their @ClinTrialsJ article: http://journals.sagepub.com/doi/abs/10.1177/1740774518792258#articleShareContainer

How can we supplement p-values as tools for the Go/No-Go decisions in Phase II trials? Satrajit Roychoudhury of @pfizer and co-authors explain in their @ClinTrialsJ article: journals.sagepub.com/doi/abs/10.1177________

An extensive review of NHLBI's cardiovascular clinical trials shows that many trials fail to achieve full recruitment success
Performance and predictors of recruitment success in National Heart, Lung, and Blood Institute’s cardiovascular clinical trials

Victoria L Pemberton, Frank Evans, Jamie Gulin, Ellen Rosenberg, Ebyan Addou, Kristin M Burns, David J Gordon, Gail D Pearson and Jonathan R Kaltman

Abstract
Background/Aims: Identifying predictors of recruitment success in clinical trials, particularly prior to study launch, could contribute to higher study completion rates and improved scientific return on investment. This article evaluates the performance of clinical trials funded by the National Heart, Lung, and Blood Institute that began recruitment before and after implementation of National Heart, Lung, and Blood Institute’s 2009 Accrual Policy and identifies study-related factors that predict recruitment success.
Methods: A retrospective analysis of National Heart, Lung, and Blood Institute’s cardiovascular clinical trials with initial funding from 1996 to 2012 was performed to assess recruitment success. Success was defined as ≥100% enrollment of the proposed sample size within the duration initially proposed by investigators. Trials were assigned to categories (pre-policy vs post-policy) based on whether the first patient was enrolled before or after the 2009 Accrual Policy implementation. Potential determinants of successful recruitment were evaluated using multivariable logistic regression.
Results: Of 167 trials analyzed, 26.3% met the definition of success. Twenty-four trials (14.4%) were terminated early and 15 (62.5%) for insufficient recruitment. Trials failed due to <100% enrollment (22.8%), longer duration (19.8%), or both (31.1%). Trials testing behavioral interventions, those conducted within a National Heart, Lung, and Blood Institute–funded network, and those with normal controls were predictive of success. The proportion of successful clinical trials increased from 23% in the pre-policy era to 30% post-policy, although the difference was not statistically significant (p = 0.29).
Conclusion: Enrollment success rates for National Heart, Lung, and Blood Institute’s clinical trials are concerning. The

Read this article to learn about the responsiveness of the military command to the logistics of conducting a clinical trial.
Lessons learned conducting a multi-center trial with a military population: The Tinnitus Retraining Therapy Trial

Roberta W Scherer¹, Leonora D Sensinger¹, Benigno Sierra-Irizarry², Craig Formby³; on behalf of the TRTT Research Group

Abstract

Background: The Tinnitus Retraining Therapy Trial (TRTT), a randomized, placebo-controlled, multi-center trial, evaluated the efficacy of tinnitus retraining therapy and its individual components, tinnitus-specific educational counseling and sound therapy versus the standard of care, in military practice to improve study participants’ quality of life. The trial was conducted at six US military hospitals to take advantage of the greater prevalence of tinnitus in the military population.

Methods: During the trial, various challenges arose that were uniquely related to the military setting. To convey these challenges to investigators planning future multi-center trials in military hospitals, we itemized various challenges that arose during the trial, interviewed clinic directors and coordinators to elicit their viewpoints, and then collated and organized their responses, together with those challenges presented while conducting the Tinnitus Retraining Therapy Trial.

Results: We encountered challenges in site selection, the approval process, administrative issues, study personnel training and retention, participant recruitment methods and issues, adherence to protocol, reimbursement issues, and military security. Site selection involved visiting 20 military hospitals to identify six sites that enrolled and followed study participants. We found that commitment for the trial must be obtained from the full military chain of command, but with ongoing changes in staff or military priorities, initial commitments were insufficient to sustain support throughout the entire trial. More time is required to obtain necessary administrative approvals by various military authorities and institutional review boards than is typically experienced in civilian settings. Recruitment strategies must be flexible due to changing military regulations regarding display of materials. Protracted periods of inactivity were due to sequestration and delays in institutional review board approval of required study personnel or protocol amendments. While mostly adherent to the protocol, study staff had difficulties in integrating study visits into the military clinical schedule. Unexpected study expenses revolved around hiring civilian study staff and obtaining associated security clearance while maintaining a consistent flow of funds to each site. The added...
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The Nominating Committee will consider all proposed candidates and, from the list of willing nominees, select a slate of candidates for the ballot. This year, the Nominating Committee consists of Sumithra Mandrekar (President), Dean Fergusson (President-elect), Jim Dignam (Board member), Will Meurer (Board member), Jenny Donovan (Member at large) and Lehana Thabane (Member at large appointed as Chair by President).

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Please contact Lehana Thabane, Chair of the Nominating Committee (thabanl@mcmaster.ca) with your nominations by COB on Monday, December 17, 2018.
EXCERPTS FROM August/Early September 2018

Open Mike

Funding Longevity by Gender Among NIH-Supported Investigators

For nearly 10 years, more women than men received PhDs in the biomedical sciences, yet women are still underrepresented at every subsequent stage of academic advancement. In 2015, for example, women earned 53% of PhDs, but they comprised only 48% of post-doctoral fellows, 44% of assistant professors, and 35% of professors. To better understand what might be contributing to women’s underrepresentation in later stages of academia, Dr. Lisa Hechtman and her colleagues at the National Institute of General Medical Sciences (NIGMS) analyzed “funding longevity by gender” among funded NIH investigators. Their analysis, recently published in the Proceedings of the National Academy of Sciences, yielded a number of interesting findings which I’d like to share with you. Continue reading →

We Want Your Feedback About Results Reporting for Basic Science Studies Involving Human Participants

We have written several blogs and articles over the past two years about our efforts to enhance stewardship and transparency in clinical trial research. Indeed, earlier this year Congress applauded our efforts thus far and reaffirmed its commitment to ensuring public access to the results of the NIH-funded clinical trials through timely registration and results information reporting on ClinicalTrials.gov. However, we have heard concern about how the NIH’s Policy on the Dissemination of NIH-Funded Clinical Trial Information applies to fundamental studies involving human participants. Continue reading →
Protecting Human Research Participants (PHRP) Online Tutorial No Longer Available as of September 26, 2018

We recently released a policy notice announcing that as of September 26, 2018, the NIH will no longer be offering the Protecting Human Research Participants (PHRP) course. It is important to note that investigators are still required to comply with all aspects of the NIH policy Required Education in the Protection of Human Research Participants, and can do so through a different training program or course. Continue reading →

Refresh Your Knowledge of Roles in eRA Commons

Have to quickly see who can do what in eRA Commons? Check out these handy guides for both at a glance and detailed information on the roles and privileges of eRA Commons users. Continue reading →

RPPRs: Who Can Do What?

A new resource, RPPRs: Who Can Do What? provides a quick look at the Annual, Interim, and Final Research Performance Progress Reports (RPPRs), including information such as due dates and how to access RPPR links. It also charts what happens to the Interim RPPR when a Type 2, Competing Renewal application is submitted.

New “All About Grants” Podcast on Valid/Stratified Analyses

For decades, NIH has required valid analysis, also known as stratified analysis, to explore how well interventions work across sex/gender and race/ethnicity for all applicable clinical trials. After revising the policy last year, NIH now requires the findings from these stratified analyses to be reported on ClinicalTrials.gov after an applicable NIH-Defined Phase III clinical trial has completed. Wondering about how this impacts your research? Continue reading →
FDA Outlines Efforts to Incorporate RWD into Drug Evaluation
In a recent article in JAMA, Jacqueline Corrigan-Curay, Leonard Sacks, and Janet Woodcock of the FDA’s Center for Drug Evaluation and Research (CDER) share steps that the agency has taken to incorporate real-world data (RWD) from electronic health records and insurance claims into clinical research. The FDA routinely uses RWD to provide evidence about drug safety and serve as historical controls, and is developing a framework for a new program to evaluate the use of RWD to support the approval of new indications for approved drugs. At the same time, further research is needed to determine when large data sets and statistical methods are sufficient to correct for systematic bias that may arise. More collaboration among clinicians, patients, health care systems, and regulators is also critical if RWD is to be effectively leveraged for public health purposes.

FDA Announces Draft Guidance on Expansion Cohorts to Expedite Drug Development
The FDA recently announced a new draft guidance for industry that provides advice to sponsors on the use of multiple expansion cohort study designs to expedite the development of cancer drugs. These trial designs employ multiple, concurrently accruing patient cohorts to assess different aspects of the safety, pharmacokinetics, and anti-tumor activity of a drug. The guidance provides FDA’s current thinking regarding products best suited for expansion cohort studies, information to include in IND application submissions, when to interact with the FDA on planning and conducting multiple expansion cohort studies, and safeguards to protect patients enrolled in these studies.

Rene Hamilton | Staff Specialist
to Leanne Madre, JD, Director of Strategy
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www.ctti-clinicaltrials.org
INNOVATION THROUGH COLLABORATION
Welcome to the September 2018 edition

This issue:
Save the Date! ICTMC 2019
HTMR Network Trial Conduct WG Webinars
HRB TMRN Webinar
HTMR Network PhD Successes
Online resource for recruitment research (ORRCA)
HRB-TMRN 4th Trial Methodology Symposium
R for trial and model-based cost-effectiveness analysis
Workshop: Joint modelling of longitudinal and survival data
Two day course: Phase I dose-finding trials
Course: Advanced STATA

Save the Date!

5th International Clinical Trial Methodology Conference, Brighton, UK
6th-9th October 2019

The HTMR Network is delighted to announce that the 5th International Clinical Trial Methodology Conference will be held in Brighton.

Please add these dates to your diary. Pre-conference workshops will once again take place as well as a varied programme that will include a wide range of themes significant to clinical trials and trials methodology.

If you would like to ensure you are on the mailing list please email.
HTMR Network Trial Conduct WG Webinar: September 2018.

27 September 2018 at 13:00

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

Summary
Following the review of 56,000 papers, an online database of articles exploring recruitment to Clinical Trials has been developed. Anna presents an exercise mapping the eligible literature against 42 recruitment themes to understand what research has been undertaken and what is yet to be explored. www.orrca.org.uk

If you wish to join this webinar, please join by click here. (Pre-registration is not required).

A recording of this webinar will be made available alongside previous webinars at: http://www.methodologyhubs.mrc.ac.uk/resources/webinars/

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.
HTMR Network PhD Successes - July 2018

Two HTMR Network funded PhD students successfully passed their viva in July.

Graham Powell, a Clinical Training Fellow at University of Liverpool, has completed his PhD titled 'An Assessment of the Use of Routinely Recorded Data in a Randomised Controlled Trial'.

The PhD research assessed the accessibility, quality, agreement and feasibility of using routinely recorded data compared to data collected using standard prospective methods in a UK RCT assessing antiepileptic drug treatments for epilepsy.

The results suggest routinely recorded clinical data in the context of prospective clinical research could be an important source of additional data, not recorded using standard methods. The use of routinely recorded data as the primary data source or as a means of validating data collected using standard methods would require careful consideration of the content, strengths and limitations of the routinely collected data variables.

Recommendations include suggestions for improving the access to routinely recorded data for research, development of an integrated electronic health record for use in both clinical practice and research and further assessment of the attributes and ‘optimal mix’ of routinely recorded data compared to data collected using standard methods.


Chris Jarvis, doctoral training fellow at LSHTM, completed his PhD on 'Spatial Analysis of Cluster Randomised Trials'.

Cluster randomised trials (CRTs) often use geographical areas as the unit of randomisation, despite this, explicit consideration of the location and spatial distribution of observations is rare.

The PhD research adopted a multidisciplinary approach to apply and evaluate spatial analysis methods in CRTs, furthering understanding of how utilising spatial analysis methods can complement traditional evaluation of CRTs.

The collective findings of this PhD thesis highlight that standard CRT approaches are typically robust to small scale spill-over effects and consideration of the spatial distribution of observations appears to provide little utility in the main analysis of a trial. Despite this, spatial methods can provide additional insights into the mechanism of interventions and are well suited to secondary analyses of CRTs, especially with the increasing collection of GPS data in CRTs.


Jarvis, Cl. et al., (2018, Accepted) Spatial Analyses of oral polio vaccine transmission in an inactive polio vaccinated Community. Clinical Infectious Diseases.
Development of an online resource for recruitment research in clinical trials to organise and map current literature (ORRCA)

Recruiting the target number of participants within the pre-specified time frame agreed with funders remains a common challenge in the completion of a successful clinical trial and addressing this is an important methodological priority. While there is growing research around recruitment, navigating this literature to support an evidence based approach remains difficult.

A large scale literature review was conducted by the HTMR Recruitment Working group and colleagues from the HRB TMRN. Following the review of 56,000 papers, ORRCA, a free, online, searchable database was developed. Included literature evaluates recruitment interventions, describes recruitment methods, and explores reasons for participation. Case studies of recruitment challenges and successes are also included.

Eligible literature was mapped against 42 recruitment themes to understand what methodological research has been undertaken and areas for future work.

Recent publication:

Kearney et al. (2018) Development of an online resource for recruitment research in clinical trials to organise and map current literature. Clinical Trials.

A free webinar discussing the results will be held on Thursday 27th September 1pm [see above](#).

This work was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/1–B2).

HRB-TMRN 4th Trial Methodology Symposium

The [HRB-TMRN](#) are holding their 4th Trial Methodology Symposium in Galway this October 11th.

The theme for this years event is "Methodological Innovations in Randomised Trials". This flagship event brings together a host of individuals with an interest in trial methodology nationally.

**Early booking is advised** to secure a place.

This event is preceded by the [2018 Winter School – Developing Best Practice for Conducting Trials of Complex and Behaviour Change Interventions in Health](#).
R for trial and model-based cost-effectiveness analysis: workshop summary

A one-day workshop on the use of R for trial and model-based cost-effectiveness analysis (CEA) was jointly organised by a consortium of researchers at various institutions (UCL, University of York, University of Oxford and Bangor University). Funding for the workshop was provided by the MRC Network of Hubs for Trials Methodology Research and the UCL Research Group Statistics for Health Economics.

The workshop aims included: exploring the use of R for CEA as an alternative to Excel and to present a wide range of technical aspects, including a discussion of the many available add-on packages to help users get the most out of R for CEA.

Details of each presentation, including abstract and slides, are available on the workshop's website.
training workshop

Funded by NW HTMR, this free workshop is relevant to clinical researchers, applied statisticians and other data analysts faced with the need to deal with non-ignorable missingness in clinical studies with longitudinal outcome data or to analyse longitudinal and time to event outcomes together.

Participants will learn about the latest methodology for joint survival and longitudinal data analysis in clinical research. You will extend your data analysis and interpretation skills to a variety of clinical applications. You will learn how to use specialised software for joint modelling in R environment.

Date and Venue:

4th October 2018 10:00-15.30, Foresight Centre, University of Liverpool

Click here to register (places are limited)

Email Dr. Ruwanthi Kolamunnage-Dona for queries related to the content of the course.
Or for queries related to reservation and venue please email here.

Two day course: Phase I dose-finding trials: practical application of new designs for statisticians - October 2018

Description: In this 2-day course you will learn about the types of novel model-based designs that are increasingly used in phase I dose-finding studies, such as the Continual Reassessment Method, and how these approaches could lead to more efficient clinical trials.

Location: Cancer Research UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London. W1T 4TJ

Course Dates: 23rd & 24th October 2018

Course Fee: Academic/government employees - £225; Industry/commercial employees - £350.

Last registration date: 15th October 2018. Places are allocated on a first-come first-served basis.

Click here for: Registration form and further information.

Click here for: Contact/Questions.

Advanced STATA Course at LSHTM November 2018

Advanced STATA: Programming and other techniques to make your life easier.

A five day course from the Population Studies Group, London School of Hygiene and Tropical Medicine.

Course Date: Monday 5th - Friday 9th November 2018

Course Fee: £1385

Audience: Researchers and other professionals, from any discipline, who regularly use Stata for analysis but want to learn how to work more efficiently. It would be particularly suited to those who are about to embark on large analyses.

Range of topics include:
Efficient ways of working using do files, commands that allow you to manipulate data and to easily create new summary variables and datasets.
Stata's commands for accessing and outputting results.
Creating new commands (programs) for Stata.

**Feedback:** The course has run since 2008 and has been a great success. Participant comments include: "I learnt so much in such a short time", "I would recommend this course" and "This has saved me months of work".

Click here for [further details and how to apply](#)
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