SCT President’s Message

Hello. I just spent the last 2 days attending the SCT/QSPI Regulatory Fall Innovation Workshop. What a great meeting. Nice location, excellent speakers and a wonderful opportunity to network. Many thanks to Janelle Charles, Joshua Chen and their program committee for all their efforts. We hope to have an in depth article on the meeting in our next newsletter.

Submissions to the joint meeting of SCT and ICTMC, to be held in Liverpool, UK May 7-10, 2017 are now closed. We had an overwhelming response this year. Contributed abstract submissions totaled more than 600 this year, 2-3 times more than we received for our most recent meetings in Montreal and the Washington DC area! The Scientific Programme, Education and Student Scholarship committees have now moved into high gear and are reviewing the submissions. Registration for the meeting is now open. Time to start making your travel plans.

The Fellows Committee, headed by Susan Halabi this year, has begun its work and is now seeking nominations. See Susan’s article for more information on how to nominate someone for this very selective honor. Each year, only ½ of 1% of the members can be selected for SCT Fellow.

If you have an article you would like us to consider for the next edition, please send it to sct@fernley.com by December 9. You can also send suggestions to us regarding articles you would like to see. We reserve the right to choose what we will include in the newsletter. That will be based on space availability, and appropriateness of content to our membership. We are unable to accept any article that we view as directly or indirectly marketing a commercial product or service.

Domenic J. Reda
SCT President
Clinical Trials Issues & Methods Articles in Medical Journals

Statistical Series in Medical Journals
By Elizabeth C. Wright, NIDDK/NIH

Several medical journals have series on statistical methods and trial conduct that should be of interest to members of the Society.

The American Journal of Clinical Nutrition started a series of articles “Best (but Oft-forgotten) Practices” in August 2015. The goal of this series is to “reinforce important scientific and statistical principles that should be useful for researchers in general and for those in nutrition in particular.” Topics include missing data, interpretation of effect sizes, multiplicity, and cluster randomized trials.

The British Medical Journal has had an article category “Research methods and reporting articles” since 2008. These articles are aimed at a general medical audience and include articles on trial content and statistical methods. Statistical topics include subgroup analyses, bootstrap resampling methods, and missing data.

JAMA introduced a series “Guide to Statistics and Methods” in July 2014. The series is designed to provide explanations about analytic approaches and methods in a language practicing clinicians can understand. The articles are published concurrently with research articles that use the same approach. Recent topics include p-values, propensity scores, noninferiority trials, and cluster randomized trials.

The NEJM inaugurated a series of articles “The Changing Face of Clinical Trials” in June 2016. These articles will address challenges that face clinical trialists. Topics include data monitoring committees, pragmatic trials and adaptive designs.

In addition to these series, other journals occasionally publish statistical articles on topics of interest to their readers.

Some of the authors may be familiar to you as they are prominent members of the Society for Clinical Trials.

Bibliography of statistical articles in medical journals in past year

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Other Journals:


Applications Open for Clinical Elective Rotations for Medical/Dental Students
Submitted by Paul G. Wakim, PhD, Chief, Biostatistics and Clinical Epidemiology Service
NIH Clinical Center

For well over a decade, the National Institutes of Health (NIH) Clinical Center has offered final-year U.S. and international medical or dental students the opportunity to participate in short-term, research-oriented clinical elective rotations on the NIH campus in Bethesda, Maryland, through its Clinical Electives Program (CEP).

What rotations are available?
Currently, the NIH Clinical Center offers a total of 34 distinct rotations designed to have participants work collaboratively either with an NIH principal investigator on a clinical research team or with an attending physician on a specialty/sub-specialty clinical or consultation service at the Clinical Center. Rotations offered constitute a wide spectrum of learning opportunities including experience with well-established disciplines such as Cardiology, Critical Care Medicine, Endocrinology, Infectious Diseases, Hematology, Medical, Surgical or Radiation Oncology, Palliative Medicine Pathology, Psychiatry, and Rheumatology, as well as more novel rotations reflecting cutting-edge research in Addiction Medicine, Alcoholism, and Sickle Cell Disorders. Additionally, beginning in the fall 2017, five newly developed 3-month (block) mentored rotations will be offered for senior level MD/DO-PhD students in Genomic Medicine, Cancer Immunotherapy, Inflammation and Inflammatory Disorders, Biomedical Informatics, and Health Services Research.

What makes NIH Clinical Center’s Clinical Electives Program unique?
The elective rotations offered through the CEP provide students with exposure to rare, complex and intellectually challenging disorders as well as the opportunity for direct participation in the practice of translational medicine at the NIH Clinical Center. Students gain additional perspective on the design and implementation of human subjects research, including phase I or phase II clinical trials during many rotations, and access to other learning opportunities, including lectures and symposia at the NIH, to advance their academic and professional development.

Application Information and Dates
The CEP has a “rolling” application process and accepts students for rotations throughout the academic year. Some restrictions on dates of participation apply for certain rotations in high demand. Applications are submitted on-line, either through the website of the NIH Clinical Center’s Office of Clinical Research Training and Medical Education at https://octrme.cc.nih.gov/cep/_layouts/OCRTME/ApplicationForm.aspx?XsnLocation=/cep/forms/ApplicationForm.aspx, or through the Association of American Medical College’s Visiting Student Application Service (VSAS) at https://students-residents.aamc.org/attending-medical-school/electives-and-make-courses/applying-away-electives-vsas.
More information about the CEP, including eligibility criteria and specific rotation descriptions, is available on-line at http://www.cc.nih.gov/training/students/clinical_electives.html or by e-mail at cc_od_octrme_cep@mail.nih.gov.

The CEP is unable to provide training stipends or housing and travel subsidies to participants in elective rotations.
Call for 2017 Fellow Nominations
Submitted by Susan Halabi, PhD, Duke Cancer Institute

Nominations due December 16, 2016

The Society for Clinical Trials established the title of “Fellow of the Society for Clinical Trials (FSCT)” in 2005 to honor Society members who have made significant contributions to the advancement of clinical trials and to the Society. This title is granted to a number of Society members each year at the Annual Meeting. Nominations for the Class of 2017 are currently being accepted. Any member of the Society may nominate a candidate, and Fellows are encouraged to nominate candidates. Complete nomination packets are due by December 16, 2016 to sct@fernley.com

Who May be Nominated
Candidates 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 SCT Fellows Committee on the basis of contributions to the advancement of clinical trials in one or more of the following areas:

• Methodologic development
• Trials coordination, conduct, or leadership of individual clinical trials
• Education
• Ethics
• Information technology, data management, or data quality
• Promotion of a better understanding by the general public of the importance of randomized clinical trials
• Service to the Society

How to Submit a Nomination
If you know someone who meets these qualifications and is deserving of this particular Society honor, please follow this three-part process:

1. Check with the SCT office at sct@fernley.com to confirm the eligibility of your intended nominee.

2. Email the Fellow Nomination Committee Chair, Susan Halabi at susan.halabi@duke.edu with the name of your intended nominee. This will eliminate duplicate nominations.

3. Prepare a Nomination Packet and send it to the SCT Office at sct@fernley.com
by the November 20 deadline. The nomination package should include: candidate’s current curriculum vitae (CV) and three or more letters of support from individuals qualified to describe the candidate’s contributions. At least two of the letters should be from individuals at an institution, agency, or organization other than that of the candidate. Please note that the nominator may request the candidate to provide a current CV, however it is the nominator’s (not the nominee’s) role to request the letters of recommendation and to prepare a cover letter (if they are not one of the authors of one of the letters of recommendation to document meeting the criteria). Please visit the SCT website for complete nomination submission details and mailing address.

Nomination packets will be reviewed and selected Fellows will be notified in February 2017. The Class of 2017 Fellows will be announced and honored at the SCT 38th Annual Meeting, May 7th – 10, 2017, in Liverpool, United Kingdom.
Dear Liverpool, Thank you For the Music!

Liverpool is well-known for its music and has recently been designated a UNESCO City of Music. It is only the second UK city to be given the status, following Glasgow. This follows Liverpool’s experience as European Capital Culture in 2008.

Liverpool is proud to be the birthplace of The Beatles and home to one of the finest orchestras in the country, the Royal Liverpool Philharmonic Orchestra who play at the beautiful art deco Philharmonic Hall. The Hall also stages contemporary and classical music by a host of famous names. During the ICTMC/SCT conference the Philharmonic Hall hosts Steve Hackett, former Genesis guitarist, and his band, and a concert of cello and clarinet music by Bach, Lindeberg, Reich and Xenakis.

‘The Fab Four’ are, of course, Liverpool’s most famous offspring and the city offers a wealth of Beatles related museums and experiences for fans including The Beatles Story at Albert Dock which tours through the Beatles’ lives, with fascinating Fab Four memorabilia and insights from friends and family. Many will be aware that the Beatles began in The Cavern Club on Mathew Street in the city centre. The Beatles played there nearly 300 times. The Cavern Club is still an advocate for new and local talent hosting live music and tribute acts daily. Many famous faces have also graced the stage at the venue including The Rolling Stones, Elton John, Queen and in more recent years Adele.

In 1960 Liverpool was the heart of The Mersey Beat, and it is officially the World Capital of Pop. The Liverpool music scene also includes the world-class Echo Arena Liverpool, which has attracted such names as Bob Dylan, Beyonce, Ellie Goulding and Dame Shirley Bassey in the past. The Arena forms part of ACC Liverpool where the ICTMC/SCT conference will be held.

Liverpool is becoming increasingly well-known for its festivals. Every year, Liverpool Sound City brings some of the most exciting breakthrough artists to the forefront. It is the largest international music, digital and film festival and conference in the UK. In 2015, Sound City was awarded The Best Metropolitan Festival at the UK Festival Awards. At the same ceremony, Liverpool International Music Festival was named Best Festival for Emerging Talent. This festival is Europe’s largest free music event. Previous year’s festivals included names such as Basement Jaxx, Katy B, Labrinth, Conrad Sewell and local Liverpool DJ Anton Powers. As you might expect, Liverpool also hosts International Beatlesweek with bands and fans from over 20 countries. As well as live events, there are exhibitions, memorabilia sales, speakers, video shows, sightseeing tours and a convention.
In addition to the recently refurbish Philharmonic Hall, Liverpool has fourteen theatres and halls. The Liverpool Empire Theatre is the second largest theatre in the country and showcases the best in local, national and international talent, often hosting shows direct from London’s West End including Billy Elliot which will be on stage during the conference. Liverpool’s Royal Court Theatre stages comedies and musicals throughout the year, with largely local casts and crews. The production at the time of the conference will be The Royal – a comedy based on the new Royal Liverpool University Hospital.

The Everyman and Playhouse theatres have been at the forefront of British theatre from their inception. Theatrical talents such as Julie Walters, Pete Postlethwaite, and Bill Nighy, all considered the Everyman a formative home in their early years. In 2014 The Everyman was awarded the RIBA Stirling Prize for best new building of the year. Shows during the conference are yet to be announced.

As you would except from the city that produced Ken Dodd and John Bishop, Liverpool also has a thriving comedy scene. Many bars, clubs and theatres host regular comedy nights such as Comedy Central Comedy Club in the Albert Dock, and Hot Water Comedy Club. Popular comics such as Jack Whitehall, Russell Howard and Miranda Hart can often be found performing at The Echo Arena.

Liverpool also offers extensive opportunities for the amateur and aspiring musician. In 1988 the University of Liverpool created the Institute of Popular Music becoming the first department in the UK to introduce dedicated, specialist popular music studies and research. With a large number of choirs and orchestras welcoming musicians of all standards and performing concerts at a range of venues within the city there is bound to be a concert to suit every taste, and every budget.

Wherever you are in Liverpool, you are never far away from music, and the arts!

Laura Bonnett
Liverpool Trivia Questions and Answers

Last month's Liverpool trivia question:
What song is Liverpool football club's anthem?

And the answer is:
You'll Never Walk Alone

The next question is:
What is unusual about the two architects who built the Anglican and Catholic cathedrals?

Check the December SCT Newsletter for the answer!