VOLUME 33,#1 NEWSLETTER JANUARY 2022

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CALENDAR OF EVENTS

Event	Date	For More Information
SCT 2021 Trial of the Year Nominations	By January 28, 2022	To submit your nomination, please click here
SCT 2022 Fellows Nominations	By January 28, 2022	Submit your candidate's Nomination Packet by clicking here
14th Annual U Penn Conference on Statistical Issues in Clinical Trials	April 12, 2022	For more information and to register, click here
Society for Clinical Trials 42nd Annual Meeting	May 15-18, 2022 San Diego, CA Registration opens soon!	http://www.sctweb.org/meeting/

Have you renewed your SCT membership for 2022?

Discover the value of becoming a member.

Click here

Call For The David Sackett Trial Of The Year Nominations

Deadline is January 28, 2022

We Are Accepting Nominations For The Trial Of The Year 2021!

Nominations must be submitted online (click here).

The Society for Clinical Trials presents an annual award to the randomized clinical trial published (either electronically or in print) in the previous year (2021 in this case) that best fulfills the following standards:

It improves the lot of humankind.

It provides the basis for a substantial, beneficial change in health care.

It reflects expertise in subject matter, excellence in methodology, and concern for study participants.

It overcame obstacles in implementation.

The presentation of its design, execution, and results is a model of clarity and intellectual soundness.

The deadline for nominations is January 28, 2022.

The Award will be presented at the 43rd Annual Meeting

taking place in San Diego, CA

May 15-18, 2022

***Nominations can be submitted online between November 2, 2021 and January 28, 2022.**

*Nominations from the Trial of the Year planning group are also welcome.

For questions, please contact SCT via **email**

CLINICAL TRIALS

Journal of the Society for Clinical Trials

December, 2021 Issue Highlights

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

By Colin Begg, Editor

In the **December** issue of ***Clinical Trials*** **Dionne Price** and **John Scott** report on the FDA Complex Innovative Design Pilot Program, an initiative to investigate the increasing complexity of clinical trial designs employed for FDA new drug applications.

Alexia Iasonos and **John O'Quigley** provide commentary on this initiative, arguing against overly complex modeling but in favor of thoughtful use of historical data.

Tyler Benning and colleagues investigate clinical trials sponsored under the Pediatric Research Equity Act, designed to encourage drug testing in children, finding that these trials have low methodological rigor and generally do not change utilization.

Finally **Matteo Quartagno, Tim Morris** and **Ian White**, in a research letter, follow up on an earlier study of the relative merits of using restricted mean survival time and the hazard ratio in the context of non-inferiority trials, providing further insights into their conflicting statistical properties.

As always we welcome submissions from SCT members about contemporary issues of relevance across the clinical trials landscape.

Call For Society for Clinical Trials 2022 Fellow Nominations

Deadline is January 28, 2022

Nominations must be submitted online (click here).

The Society for Clinical Trials established the title of "Fellow of the Society for Clinical Trials" 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 are currently being accepted and any member of the Society may nominate a candidate. **Complete nomination packets are due by January 28, 2022**. The Class of 2022 Fellows will be announced and honored at the SCT 43rd Annual Meeting to be held May 15-18, 2022 in San Diego, California.

Who May be Nominated

The Society actively encourages the submission of nominations representing both the full diversity of persons deserving of recognition and representing all areas of contribution supporting excellence in the conduct of clinical trials.

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:

- Design, coordination, analysis and/or reporting of oversight of individual or multiple clinical trials.
- Education and promotion of a better understanding by the general public of the importance and interpretation of randomized clinical trials.
- Ethical considerations and human subjects' protections in the conduct of clinical trials.
- Information technology, data management, data quality, or data sharing.
- Service to the Society.

How to Submit a Nomination

Please visit the SCT **website** for complete nomination submission details.

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

- Contact the SCT office via **email** to confirm the eligibility of your intended nominee.
- Prepare a Nomination Packet **by the January 28, 2022 deadline.**
- Submit your candidate's Nomination Packet by clicking **here**

The nomination package should include:

- Current curriculum vitae (CV) or resume.
- Three or more letters of support from individuals qualified to describe the candidate's contributions:
    1. May include a letter of support from the nominator.
    2. At least two of the letters should be from individuals at an institution, agency, or organization other than that of the candidate.
- Cover letter to document meeting the criteria. If the nominator writes a letter of support, documentation of meeting criteria may be incorporated into the letter of support instead

Nomination packets will be reviewed by the SCT Fellows Committee and selected Fellows will be notified in early 2022.

In Memory of Elizabeth Thom

We received the following very sad news about the passing of Elizabeth Thom in December.

Dear staff of the Biostatistics Center:

We are all deeply saddened by the passing of Elizabeth Thom, former Director of the Biostatistics Center, who passed away on December 8, 2021. We would like to provide some highlights of Liz's career and recognize her many contributions to improving the health of mothers and babies across the globe and her contributions to the Center.

Liz came to the Center in 1986 as a Research Associate. She received her B.A. and M.A in Mathematics from the University of Oxford, UK and an M.Sc. in Biometry from the University of Reading, UK. In 1992 she completed her PhD in Mathematical Statistics at GW. For over 30 years she worked on the Eunice Kennedy Shriver National Institute of Child Health and Human Development's Maternal Fetal Medicine Units (MFMU) Network. She ultimately became the PI of the Network Data Coordinating Center and served in that role for 20 years.

Liz provided excellent leadership to the Biostatistics Center. She was first appointed to the Center's Executive Committee in 2002 and later named Associate Director in 2009. In November, 2012 she became the Director and served in that role until April of 2018.

Liz had extensive experience in the design, conduct, analysis, and reporting of multi-center clinical studies, in particular randomized trials in obstetrics and fetal diagnosis and therapy. During her time at the Center she was the Principal Investigator or Co-Principal Investigator of several major impactful studies including:

1. A randomized Trial of 11 - 14 week Amniocentesis and Transabdominal CVS: Data Coordinating Center, 1996-2001

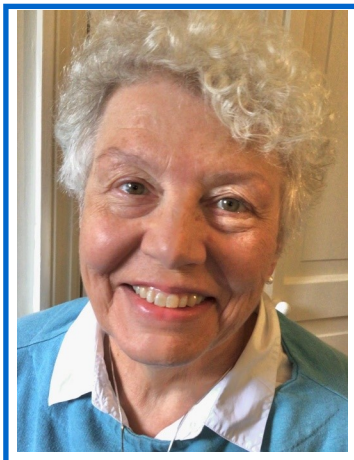
2. The Management of Myelomeningocele Study (MOMS) trial evaluating prenatal vs. postnatal repair of spina bifida, 2002-2012, and a Follow-up of Children Enrolled in the Management of Myelomeningocele Study, 2011-2018, which showed that pre-natal surgery reduced the need for shunting and improved motor outcomes. Prenatal surgery is now available at several specialist centers in the US. MOMS was selected by the Society for Clinical Trials as the Trial of the Year in 2012.

3. The Prenatal Cytogenetic Diagnosis by Comparative Genomic Hybridization (CGH) Microarray – DCC, 2007-2012, a study recognized in the Clinical Research Forum's Top Ten Awards.

4. The Research Coordinating Unit for the Lifestyle Interventions in Overweight and Obese Pregnant Women Consortium (LifeMoms), 2011-2019

5. The Eunice Kennedy Shriver National Institute of Child Health and Human Development's Maternal Fetal Medicine Units (MFMU) Network. The MFMU conducts clinical research in maternal-fetal medicine and obstetrics with the aim to: 1) reduce the rates of preterm birth, fetal growth abnormalities, newborn morbidity, and maternal complications of pregnancy; and 2) evaluate maternal and fetal interventions for efficacy, safety, and cost-effectiveness. The MFMU comprises 160,000 deliveries/year representing 4% of the US population. Liz served as the PI of the MFMU Network from 1998 to 2018. A total of 58 studies have been conducted under MFMU: 33 clinical trials and 25 observational studies. Some of the most important are:

   a. The Beneficial Effects of Antenatal Magnesium Sulfate (BEAM) trial (1997-2007), a randomized, controlled trial of magnesium sulfate for the prevention of cerebral palsy for which preterm birth is a risk factor. The trial showed a 45% reduction in moderate to severe cerebral palsy for women that were given IV magnesium sulfate. The ACOG and the SMFM Committee on obstetric



In Memory of Elizabeth Thom (Continued)

practice recommended that magnesium sulfate be given before anticipated early preterm birth. It is now routinely given to women. The trial was highlighted in Time Magazines' The Year in Medicine in 2008.

b. A RCT of 17-alpha-hydroxyprogesterone Caproate for Prevention of Preterm Birth in High Risk Women (1998-2002) which demonstrated that 17 alpha hydroxyprogesterone caproate reduces the risk of recurrent preterm birth.

c. An Observational Study of Cesarean Section and Vaginal Birth After Cesarean Section, 1999-2002

d. A Randomized Placebo-Controlled Clinical Trial of Antenatal Corticosteroid Regimens (BEARS), 2000-2006

e. A RCT of Treatment for Mild Gestational Diabetes Mellitus (GDM), 2002-2008

f. A RCT of Thyroxine Therapy for Subclinical Hypothyroidism or Hypothyroxinemia Diagnosed During Pregnancy, 2006-2015, a study that received the 2016 Norman F. Gant Award for the best research in maternal medicine.

g. A Randomized Trial of Antenatal Late Preterm Steroids (ALPS) – DCC, 2011-2015, and the Pulmonary Complications and Neurocognitive Development in a Birth Cohort after a Randomized Trial of Antenatal Corticosteroids: the ALPS Follow-Up Study - Data Coordinating Center, 2016-2021, which demonstrated that antenatal corticosteroids given in the late preterm period reduces neonatal respiratory morbidity.

h. A Randomized Controlled Trial of Pravastatin for the Prevention of Preeclampsia in High Risk Women; Data Coordinating Center, 2018-2024

Since its inception, the MFMU Network has published about 375 papers. Liz was personally an author of 114 publications, 19 of which were in the *New England Journal of Medicine*. The results of Network studies have been used to form recommendations for clinical care, including the American Congress of Obstetricians and Gynecologists (ACOG) Practice Guidelines and Committee Opinions and statements from the Society for Maternal-Fetal Medicine. The Management of Myelomeningocele Study (MOMS) trial was named "Trial of the Year" by the Society for Clinical Trials in 2012 and cited as "an important clinical trial that overcame extraordinary difficulties and produced remarkable results."

During her time as a Principal Investigator at the Center, through the projects listed above, Liz brought in nearly $200 million in research funding. Although we do not have an accurate count of the number of staff employed on her projects throughout all the years, it is believed to be between 100 to 200 people.

Liz mentored many throughout her career, including serving as the Dissertation Director for Rebecca Clifton, Cora MacPherson, and Sharon Gilbert and she served on the Dissertation Committee for Greg Sandoval. Her impact as a distinguished researcher is further seen through those faculty and maternal fetal medicine fellows she mentored over several decades ensuring her knowledge and legacy will continue for generations. For over 25 years she taught a workshop on clinical trial design in perinatal medicine at the annual NICHD conference on maternal-fetal-neonatal medicine, and for several years she taught workshops on research study design for the Society for Maternal Fetal Medicine Annual Fellows Retreat. The purpose of these workshops was to encourage fellows and junior faculty to have a career in research in maternal-fetal medicine and neonatology. Many of the participants came from Network Centers and have gone on to impressive careers. She enjoyed mentoring these young investigators and found it very rewarding.

Liz was a Fellow of the Society of Clinical Trials, received the NICHD Duane Alexander Award for Academic Leadership in Perinatal Medicine, and the 2020 GW Distinguished Researcher Award. She served on

In Memory of Elizabeth Thom (Continued)

numerous data and safety monitoring committees, advisory committees and NIH peer review panels. She served as the Chair of the Intramural Data and Safety Monitoring Board for the National Human Genome Research Institute, the Chair of the Stillbirth Network Advisory and Safety Board of the NICHD. She served on the Data and Safety Monitoring Committee for the WHO Study Screening for Preeclampsia and the Prenatal Alcohol in SIDS Advisory and Safety Board. She was a member of the Society for Maternal Fetal Medicine and a member of the Board of Directors for the Society for Clinical Trials.

Liz was a giant in her field, internationally recognized as the pre-eminent biostatistician in maternal-fetal medicine, a distinguished researcher who contributed in immeasurable ways to the improvement of obstetric and perinatal care, and to fetal diagnosis and therapy. Although she was extremely dedicated and had many accomplishments, Liz would not approve of getting too much praise or attention. In her typical British manner, she was quite understated about her achievements. She was a major source of strength for those who worked under her and her research was a financial pillar for the Center. Beyond her many career accomplishments Liz was a wonderful human being, consistently kind, thoughtful and polite. She was amazingly calm in the face of crises and deadlines. She was a friend to many and provided experienced advice and wisdom on many topics. She enjoyed the opera, playing the cello and loved gardening. She was a truly lovely person. We will miss her immensely.

In remembrance of our colleague whom we loved and respected,

Scott Evans

Director, The Biostatistics Center

and

Katrina Billingsley

Director of Administration, The Biostatistics Center

Her Contributions to Society for Clinical Trials

- Fellows Committee Chair (2020-2021)
- Board of Directors (2017-2021)
- Member, Management Firm Search Committee (2019)
- Fellow (2018)
- Trial of the Year Winner (2012)
- Contributed Sessions (2011, 2012)
- Continuous membership since 2010

Fellows Citation

For leadership of multiple multi-center randomized trials in obstetrics, maternal-fetal medicine and fetal therapy which have had an impact on clinical practice both in the US and globally, for mentorship of clinical investigators and service to the society

Thank you Liz!

14th Annual UPenn Conference on Statistical Issues in Clinical Trials Subgroup Analysis in Clinical Trials: Opportunities and Challenges April 12, 2022 Registration Now Open

The SCT is continuing its long standing collaboration with the Department of Biostatistics, Epidemiology and Informatics at the University of Pennsylvania and is delighted to announce the 14th Annual Conference on Statistical Issues in Clinical Trials - Subgroup Analysis in Clinical Trials: Opportunities and Challenges.

Tuesday, April 12, 2022 - 8:30am to 4:30pm
Virtually via BlueJeans
For additional information about the conference and to register, click here.

MORNING SESSION

David Kent, MD (Tufts University)
Overview: Overall average treatment effects and one-variable-at-a-time subgroup analysis: The Scylla and Charybdis of Evidence Based Medicine

Ellis Unger, MD (Consultant)
An "unofficial" US Regulatory Perspective

Tom Fleming, PhD (University of Washington)
Pitfalls of subgroup analysis

Lisa McShane, PhD (NCI)
Finding the subgroup of patients who benefit from a novel therapy: no time for a game of hide and seek

AFTERNOON SESSION

Noah Simon, PhD (University of Washington)
Adaptive Enrichment Trials: Identifying the 'right' subgroup

Anastasia Ivanova, PhD (UNC)
Antimicrobial prophylaxis for vesicoureteral reflux: which children benefit the most?

Ilya Lipkovich (Eli Lilly)
Comparison of recent approaches for subgroup identification from clinical and observational data

Patrick Schnell, PhD (Ohio State)
Multiplicity considerations for analyses of non-exchangeable subgroups

PANELISTS
Mark Rothmann (FDA)
Kosuke Imai (Harvard)
Kit Roes (European Regulatory Perspective)
Michael Rosenblum (Johns Hopkins)
Janet Wittes (Statistics Collaborative, Inc.)

Society for Clinical Trials
is Pleased to Announce the Launch of the
DATA MONITORING COMMITTEE INITIATIVE

Dear SCT Members and Clinical Trials Community:

I am pleased to announce that SCT is launching the Data Monitoring Committee (DMC) initiative. It was born out of our recognition that there is a dearth of people qualified to serve on DMCs. Dr. Dave DeMets, a long-time SCT member and Dr. Dean Fergusson, Past SCT President, initiated this discussion in 2019 and a planning committee was formed by our then-president Dr. Susan Halabi including key opinion leaders from SCT leadership, industry, academia, and government. At the same time, TransCelerate Biopharma, a non-profit biopharmaceutical research and development organization, was working towards a similar goal for some time and we decided to join forces. Copyrights for this initiative were transferred from TransCelerate to SCT in 2021.

The initiative we are launching today is the product of these efforts and contain three components:

(1) Training: Several lectures were developed under the leadership of Dr. Dave DeMets featuring speakers who are world leaders in the science and practice of DMCs. Their videos are available free of charge at SCT's web site (www.sctweb.org/dmctraining).

(2) Registry: There is a registry for individuals who are interested in serving as DMC members (www.sctweb.org/dmcregistry). Dr. Haley Hedlin and Dr. Andreas Sashegyi, both members of the planning committee led the charge to develop this registry with significant effort from TransCelerate. Any individual can register indicating their interest and providing information on how much, if any, experience they have on this topic.

(3) Mentoring: Using the information from the registry we will offer mentoring opportunities to those who need it provided by experienced members.

We envision that this initiative will help to serve the unmet need in creation and functioning of DMCs, and serve as a resource for our members as well as the clinical trials community. This would not have happened without Dr. Dave DeMets' vision, intellectual and organizational leadership, and Dr. Susan Halabi's vigorous support of the initiative and channeling of the necessary resources. On behalf of SCT's Executive Committee and Board of Directors I am thanking them and all the members of the planning committee listed at the end of this message.

I invite all of you to participate by enrolling in the DMC registry, using the training modules, and partaking in the mentoring component. We welcome any feedback that you might have on this initiative.

Mithat Gönen
SCT President

Members of the Planning Committee:
Dave DeMets, PhD (University of Wisconsin-Madison)
Andreas Sashegyi, PhD (E. Lilly)
Haley Hedlin, PhD (Stanford University)
Ray Bain, PhD (Merck)
Karim Calis, PharmD (National Institute for Child Health and Human Development /NIH)
Barry Davis, MD, PhD (University of Texas in Houston School of Public Health)
Susan Ellenberg, PhD (University of Pennsylvania)
Scott Evans, PhD (George Washington University)
Thomas Fleming, PhD (University of Washington-Seattle)
Chris Granger, MD (Duke University /Duke Clinical Research Institute)
Mithat Gönen, PhD (Memorial Sloan Kettering Cancer Center)
Susan Halabi, PhD (Duke University)
Ed Korn, Ph.D. (National Cancer Institute)
William Meurer, MD (University of Michigan Medical School)
Pralay Mukhopadhyay, PhD (Otsuka America Pharmaceuticals, Inc.)
James Neaton, PhD (University of Minnesota)
Michael Proschan, PhD (National Institute for Allergy and Infectious Diseases)
Jean Roleau, MD (University of Montreal)
Frank Rockhold, PhD (Duke University/DCRI)
Peter Sandercock MD, (University of Edinburgh)
Janet Wittes, PhD (Statistics Collaborative)

Society for Clinical Trials Board of Directors

Kaleab Abebe

Kaleab Abebe is an Associate Professor of Medicine, Biostatistics, and Clinical & Translational Science at the University of Pittsburgh. He directs the Center for Research on Health Care Data Center as well as the Center for Clinical Trials & Data Coordination. Dr. Abebe joined the faculty in 2009 after receiving his PhD in Statistics from the University of Pittsburgh. His collaborative research focuses on design, conduct, coordination, and analysis of multicenter randomized controlled trials (RCTs). He is the PI of two, large NIH-funded consortiums: the COPE-AKI Consortium Scientific & Data Research Center, which is developing and testing interventions to reduce morbidity and mortality in AKI survivors; and the Data Coordinating Center (DCC) for the REBIRTH Study, which will assess the effect of bromocriptine on left ventricular ejection fraction in women with peripartum cardiomyopathy. He is the Co-PI for the CaRISMA study, which is a pragmatic trial examining the effectiveness of computerized cognitive behavioral therapy (vs pain education) on pain intensity in adults with sickle cell disease (SCD). Dr. Abebe leads the DCC for the STERIO-SCD study, a phase II trial evaluating safety and tolerability of riociguat in SCD. Most recently, he led the DCC for the TAME-PKD study, which was a phase II RCT assessing safety and tolerability of metformin in polycystic kidney disease (PKD). Additionally, Dr. Abebe collaborates with the Adolescent Medicine Division on the design and analysis of cluster randomized trials in sexual violence prevention. In addition to his research collaborations, Dr. Abebe is the director of the Clinical Trials Track for the MS in Clinical Research at the Institute for Clinical Research Education. He is a standing member of the Kidney, Nutrition, Obesity, and Diabetes (KNOD) Study Section, and he is a member of the Board of Directors and chair of the Equity, Diversity, and Inclusion committee for the Society for Clinical Trials.

Emily Dressler

Emily Dressler is an Associate Professor and Vice Chair of the Department of Biostatistics and Data Science at Wake Forest School of Medicine. She is the lead biostatistician with the WF NCI Community Oncology Research Program (NCORP) Research Base, a faculty member in the Biostatistics Shared Resource at the WF Comprehensive Cancer Center, and the current lead biostatistician for iDAPT: Implementation and Informatics - Developing Adaptable Processes and Technologies for Cancer Control - Research Program. She earned my PhD in the Division of Biostatistics at the Medical University of South Carolina. Previously at the University of Kentucky Markey Cancer Center, where she developed expertise designing and analyzing phase I/ phase II single-center investigator-initiated cancer treatment trials. Her primary methodological research interest is in clinical trials, specifically adaptive designs. She has expertise in the design of Phase I trials using model-based, adaptive strategies such as the continual reassessment method and developed methods that are variants of this design to incorporate ordinal toxicity grading and with mixed toxicity/efficacy dual outcomes. As the lead biostatistician for WF NCORP, Dr. Dressler oversees and assists with study design, randomization, monitoring, data intake/management and interim/final analyses where applicable for our portfolio of studies. She is an active member of the Society for Clinical Trials, currently serving of the Board of Directors and previously as education committee chair. Additionally, she is an active member of AACR, ASCO, and ASA, currently serve on the ASCO Research Committee, and was a faculty member for the ASCO/AACR Methods in Clinical Cancer Research Workshop.

Dixie Ecklund

Dixie J. Ecklund, RN, MSN, MBA is the Director of Operations for the University of Iowa Clinical Trials Statistical & Data Management Center (CTSDMC) which has served as the DCC, the CCC, and/or the Statistical Core for the NIH-funded Clinical Islet Transplantation (CIT) Consortium, the CHAMP study, NeuroNEXT, A2CPS, and FM TIPs as well as the Michael J. Fox-funded PPMI. Ms. Ecklund's career at the University of Iowa spans over 40 years. She has over 30 years of experience in conducting clinical trials through the CTSDMC and in her previous role as Nurse Manager of the General Clinic Research Center (GCRC). She has been involved in various capacities in hundreds of clinical trials,

Society for Clinical Trials Board of Directors (continued)

ranging from small Phase 1 safety studies to large multi-center Phase 3 efficacy studies. She has extensive administrative experience with responsibilities including protocol design, implementation, and compliance, safety management, resource allocation, and collaboration with multiple partners. Ms. Ecklund has served as a member of the Institutional Review Board (IRB) for over 25 years and was appointed an IRB chair in 2009. She established the Central IRB at the University of Iowa for A2CPS and FM TIPS. Ms. Ecklund serves as the liaison for the NeuroNEXT DSMB, the FM TIPS DSMB, and assisted in the design and implementation of the A2CPS Safety Monitoring Committee. Ms. Ecklund has assisted in the preparation of numerous DSMB reports (open and closed) and attended numerous DSMB meetings as a DCC representative.

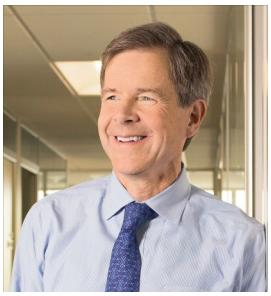
Denise Esserman

Denise is a Professor of Biostatistics at the Yale School of Public Health and co-Director of Yale Center for Analytical Sciences (YCAS) and Director of the YCAS's Methodology Core. She developed this methodology core to address the growing methodological challenges with clinical trial design encountered at Yale University and beyond. She received a methodology award from the Patient Centered Outcomes Research Institute (PCORI) to advance methods for the design and analysis of two-stage clinical trials for patient preference, selection and treatment effects. She is multiple-PI on an NIH HEAL (Helping End Addiction Long-Term) award. She is in an expert on the use of electronic health records in clinical trials – and presented on this topic at the Penn Clinical Trials Symposium. She is currently on the Board of Directors for the Society for Clinical Trials and has served as a member of the Chalmers Scholarship Committee for 4 years. She also serves on numerous data safety monitoring boards. Her mission is to train the next generation of biostatisticians and clinical trialists

Alexia Iasonos

Dr. Iasonos has been at Memorial Sloan Kettering Cancer Center since 2005. She has collaborated primarily with investigators studying ovarian cancer and also with investigative teams studying bladder cancer, lymphoma, and health outcomes. Through her collaborations with investigators in gynecology (Departments of Surgery, Medicine and Pathology) she is exploring various biomarkers and assessing relationships to histology, metastasis and clinical outcome. She is also involved in vaccine trials as a second line therapy in ovarian cancer patients, and in identifying valid endpoints for these trials. Her methodological interests focus on model-based designs that guide the dose escalation in phase I trials and in the past few years she has focused on the design of early phase trials that involve dose expansion cohorts.

Robert Lindblad



Dr. Lindblad is currently a consultant for the Emmes Corporation LLC (Emmes) where he served as the Chief Medical Officer and Director of Safety and Regulatory Affairs for 20 years. He was the Principal Investigator (PI) for multiple large multi-center NIH networks including NIAID, NHLBI and NIDA. He took the lead in safety monitoring, establishing MedDRA coding, WHO drug coding, developing a comprehensive safety reporting system and a state-of-the-art multi-relationship electronic document storage regulatory tracking system. He has numerous publications in substance use disorder, food allergy, cell therapy and infectious disease research. Prior to joining EMMES, Dr. Lindblad served as Medical Officer at FDA, Center for Biologics and Evaluation Research, Division of Therapeutic Trials and Application, Branch of Immunology and Infectious Disease. In addition, Dr. Lindblad was board certified in Emergency Medicine with a career spanning 35 years and most recently practiced at Suburban Hospital in Bethesda, Maryland,

Letitia Perdue

Letitia Perdue is a Senior Research Associate in the Department of Biostatistics and Data Science, Division of Public Health Sciences at Wake Forest School of Medicine. She has more than 20 years of experience in clinical trials research and has served as the Lead Project Coordinator of the Coordinating Center for many multicen-

Society for Clinical Trials Board of Directors (continued)

ter clinical trials, including the Systolic Blood Pressure Intervention Trial (SPRINT), Habitual Diet and Avocado Trial (HAT), the international Type 1 Diabetes Genetics Consortium (T1DGC) and the PRagmatic EValuation of evENTs And Benefits of Lipid-lowering in oldEr Adults (PREVENTABLE). She has over five years experience serving on the IRB at Wake Forest University. Throughout her career, she has worked on genetic studies, behavioral intervention trials, medication-based trials, international multicenter trials, and industry and government funded trials.

Pamela Tenaerts

Dr. Tenaerts is Chief Scientific Officer at Medable, She directs research to help identify, implement and make ubiquitous responsible decentralized trial strategies. Dr. Tenaerts brings more than 30 years of experience in clinical trials, as a researcher and academic, in medical device research operations, a hospital based site administrator, and physician, most recently serving as executive director of the Clinical Trials Transformation Initiative (CTTI) at Duke University. She sits on the board of the Society of Clinical trials, the Scientific Leadership Council of the Digital Medicine Society, participates on the Good Clinical Trial Collaborative, and is a member of the National Academies of Science and Medicine: Forum on drug discovery, development and translation. She received her MD from the Catholic University in Leuven and her MBA from the University of South Florida.

Juliana Tolles

Juliana Tolles, M.D, M.H.S. is an Assistant Professor of Emergency Medicine at the David Geffen School of Medicine at UCLA and practices clinically at Harbor-UCLA Medical Center in Los Angeles. She attended medical school at Yale University School of Medicine, where she also received a Master of Health Sciences and completed a Doris Duke Fellowship in clinical research. She completed both her residency in emergency medicine and research fellowship at Harbor-UCLA Medical Center in Los Angeles. She is an investigator for the Strategies to Innovate Emergency Clinical Care Trials (SIREN) network, an initiative jointly sponsored by NINDS, NHBLI, and NCATS to improve early intervention for neurologic, cardiac, respiratory and hematologic emergencies. She is also a medical and statistical scientist for Berry Consultants, a consulting group specializing in Bayesian approaches to medical statistics. Her areas of research interest include emergency medical services, resuscitation medicine, pediatric devices, and trauma care.

Next Newsletter: The Executive Committee members of the Board of Directors

CALLING ALL SCT HISTORIANS AND HISTORY BUFFS

The stated purpose of the Society is an international multidisciplinary organization dedicated to the development and dissemination of knowledge about the design, conduct, analyses, and reporting of clinical trials and related health care research methodologies. To this end, SCT is launching an initiative to capture missing newsletters and the information that they contain.

SCT is looking for copies of SCT Newsletters from 1978 when the Society was founded through 1997. Newsletters from 1998 to 2021 are currently available on the website at http://sctweb.org/newsletter.cfm

Do you have any of these Newsletters? We welcome you to scan and email them to info@sctweb.org.

If you prefer to mail your copies, please send them to:

Society for Clinical Trials
ATTN: Lisa Aguado
85 W. Algonquin Road – Suite 550
Arlington Heights, IL 60005

Questions? Please contact us at info@sctweb.org

Thank you for your dedication to SCT and for your help in preserving our history.

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Frontier Science Foundation is a not-for-profit research organization dedicated to the improvement of data management and statistical quality in clinical trials and medical research.

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The GW Biostatistics Center has a 47 year history of leadership in practice-changing clinical trials and biostatistical methodology research. Center research has been recognized in reports to the US President and Congress and resulted in over 60 NEJM publications.

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Silver Sponsor

BERRY CONSULTANTS

Berry Consultants is a statistical consulting company specializing in innovative clinical trial design, Bayesian analysis, adaptive clinical trial execution, and simulation software solutions for the pharmaceutical and medical device industry.

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Emmes collaborates with clients to produce valued, trusted scientific research. We are passionate about making a difference in the quality of human health, and have supported more than a thousand studies across a diverse range of diseases since our formation in 1977.

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Save the Dates - Upcoming SCT Annual Meetings

43rd Annual Meeting
May 15-18, 2022
San Diego, California

44th Annual Meeting
May 21-24, 2023
Baltimore, MD

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