SOCIETY FOR CLINICAL TRIALS

VOLUME 32,#2 MAY 2021

INSIDE THIS ISSUE:



# Welcome from SCT President Mithat Gönen

**Mithat Gönen**
**Society for Clinical Trials President 2021-2022**

Dear SCT Members,

I will begin my first column as your president by thanking every one of you for your trust. I will do my best to deserve it and I am acutely conscious of the responsibility it brings. Luckily I am surrounded by a very able team: the Board of Directors, the Executive Committee, chairs and members of the 11 standing committees and many of you whom I know will agree to help if needed, even though you may not carry an official SCT title, appointment or responsibility.

The pandemic has affected SCT in many adverse ways. We had to convert our 2020 Annual Meeting to online with very little warning, lost substantial associated revenue and perhaps more importantly saw our membership numbers decline. Things for 2021 did not look up at first: our contract with the Chicago venue precluded us from announcing an online meeting until late in the game, perhaps as a result submissions started slowly and so did registrations. When we were finally able to announce that the meeting would be online we knew we had to find the right contractor for building us a high-quality online platform that was easy to navigate. It is amazing that Susan Halabi, our 2020-2021 President, does not look worse for the wear as she led the Society through one of the most difficult periods in its existence. I am glad to report a happy ending. Our 2021 Annual Meeting was a resounding success. With 520 registrants from 15 countries, our numbers came right in the middle of those for the past five meetings (excluding 2020), we were able to meet all of our financial obligations and even put some money aside for the future. The outstanding scientific and educational program organized under the leadership of Jonathan Cook and Michael Grayling no doubt played a big role in this success, reminding us that scientific excellence is the fundamental building block for SCT's future that we cannot forsake for any reason.

I, thus, feel justified to look ahead with optimism. We are likely to have an in-person meeting in San Diego in 2022, our first since 2019. We have a great president-elect in Lehana Thabane who shares the SCT ideals, three new Board members, Dixie Ecklund, Denise Esserman and Juliana Tolles, and a freshly reappointed treasurer, Li Chen. All of this lightens the pain of Dean Fergusson to whom SCT is indebted, departing the Executive Committee, having completed his three-year presidential cycle. A third of the registrants for the 2021 meeting were first-time attendees. This means fresh faces, new

## SCT 2021-2022 President Welcome (continued)

ideas and much-needed energy. We need to focus on turning them into long-term members. By the same token the number of member registrations stood at an all time low. We need to understand why we are unable to serve the needs of those who did not attend and lure them back. Thinking a little more broadly, we need to take advantage of the silver lining in the pandemic, the momentum that carried clinical trials onto newspaper pages, television news hours, podcasts and dinner conversations. This creates many opportunities for us in public education, professional training and mentoring young clinical trialists. And we should do these while we continue to generate revenue for the Society so that we can rebuild our rainy-day funds which carried us through the dark days of 2020.

The previous paragraph summarizes my goals for 2020-2021: build a stronger member base, increasing our reach and footprint in the world of clinical trials, and regaining our financial footing. Reaching these goals will take initiatives that I will develop over the next few months, working with the leadership and the membership. Please reach out to SCT by email (info@sctweb.org) or Twitter (@SCTorg) with your suggestions, concerns and feedback. Help us carry SCT into the future.

With best wishes,

Mithat Gönen

# VITAL STATISTICS
# SCT 2021 Virtual Annual Meeting

Sessions

2 Keynote Addresses

Trial of the Year

2021 Class of Fellows

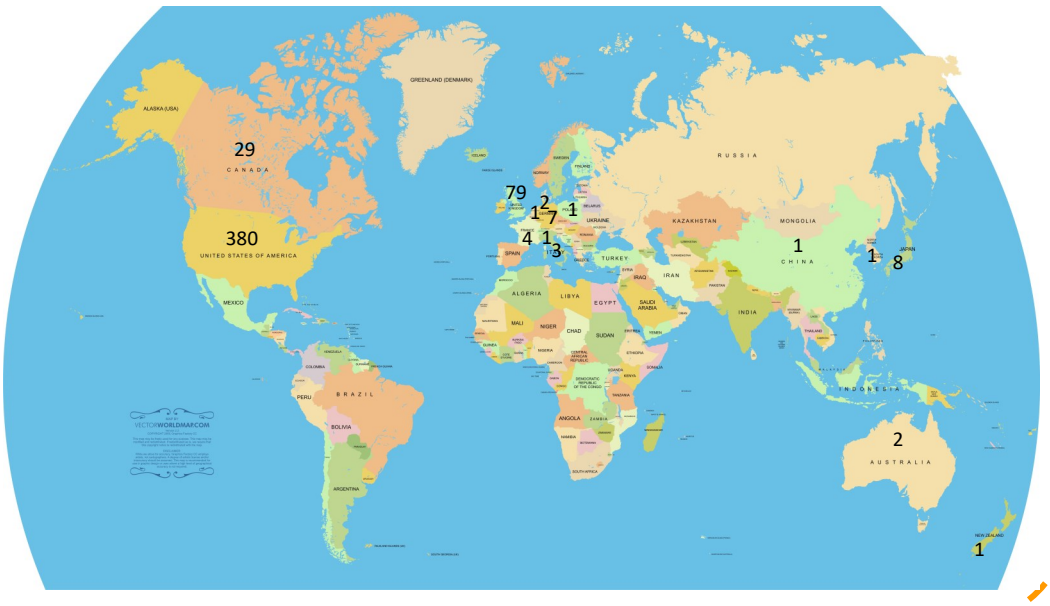
25 Sessions

75 Contributed Talks

27 On-Demand Posters

6 Workshops

| | Members | Non-Members | Total |
|---|---|---|---|
| Full Registration | 190 | 250 | 440 |
| Student Registration | 22 | 58 | 80 |
| Total | 212 | 308 | 520 |
| Workshops | | | 145 |



# Results of 2021 SCT Elections

**Nominating Committee Members:**

**Virginia Howard**
**Chair**

**Susan Halabi**
**President**

**Mithat Gönen**
**President-Elect**

**Kaleab Abebe**
**Board Member**

**Alexia Iasonos**
**Board Member**

**Chengjie Xiong**
**Member-at-large**

**Virginia Howard**
**Chair**
**Nominating Committee**

The Nominating Committee of the Society for Clinical Trials is charged with identifying candidates willing to stand for election to fill positions as President-elect and on the Board of Directors. Board members serve a four-year term; the President-elect serves one year in that role before becoming President and one additional year as Past President.

According to the Society's Bylaws (Article II, Section 4), the Nominating Committee includes the current SCT President and President-Elect, two (2) members from the Board of Directors; and three (3) from the membership of the Society at large, including the Chair of the Committee. (This year, one member-at-large dropped off the committee due to a conflict.

The Nominating Committee was formed in Summer 2020 and began its work afterwards by identifying possible candidates. A solicitation was also sent out to all SCT members in December, inviting nominations. A list was drawn up, eligibility checked, and then prioritized by the Committee members. Two candidates for President-Elect and six candidates for the three Board of Directors vacancies were identified. After ensuring that all the candidates were willing to stand for election and to serve if elected, candidates were contacted to fill out the SCT biosketch form. After minimal formatting, the SCT biosketches of the candidates were submitted to EAI, the management company for SCT, in February for balloting. The online election was held during March , 2019, with all current SCT members eligible to vote.

Here are the results.

## President-Elect

**Lehana Thabane**
**SCT President-Elect**
**2021-2022**

**Lehana Thabane, MSc, PhD**, Vice-President Research at St Joseph's Healthcare—Hamilton and Scientific Director of the Research Institute of St Joe's Hamilton, Hamilton (Ontario, Canada). He is also a Professor of Biostatistics and former interim chair of the Department of Health Research Methods, Evidence, and Impact, Associate member of the Departments of Pediatrics, Surgery, Medicine, Family Medicine, and Anesthesia; Schools of Nursing, and Rehabilitation Sciences at McMaster University (Hamilton, Ontario, Canada)

He has been a lead biostatistician for over 200 trials; chair of data safety monitoring boards for over 20 trials, and clinical trials mentor for the Canadian Institutes of Health Research RCT mentorship program.

His service to SCT includes:

Current Chair, SCT Equity, Diversity & Inclusion Committee

Member, SCT Fellows Committee

Member, SCT 2021 Annual Task Force

Past Chair, SCT Nominations Committee

Past Chair, SCT Equity, Diversity & Inclusion Task Force

His primary goals for SCT include:

*To establish a mentorship program* with a full registry of potential mentors willing to support young clinical trialists around the globe;

*To enhance the reach* of SCT through outreach to high schools, and different university programs in public health, epidemiology, biostatistics; and

*To foster an equitable, diverse and inclusive* culture in clinical trials by

Establishing a framework for meaningful patient involvement in trials;

Fostering the sharing of best EDI practices in trials;

Facilitating diverse leadership in SCT through mentorship

# SCT 2021 Elections (continued)



**Board of Directors**

**Dixie Ecklund**
**Board of Directors**
**2021-2025**

**Dixie J. Ecklund, RN, MSN, MBA** is Director of Operations, Clinical Trials Statistical & Data Management Center (CTSDMC), Department of Biostatistics, College of Public Health, University of Iowa, Iowa City, IA

Her main research interests include clinical trial operations, data management efficiencies, neurological disorders, diabetes, islet cell transplantation, protection of human subjects, and central IRBs.

Her service to SCT includes:

Educational workshops 2010-2016, 2019; Invited sessions 2013, 2014, 2018; SCT/QSPI Program Organizing Committee 2014; Nominations Committee 2014 and 2016; Education Committee 2015-2016; Program Committee 2017-2019; Membership Committee 2018-present;.

Ms. Ecklund is a member of several different professional groups but feels that she has truly found her niche with Society for Clinical Trials. The diversity of the membership appeals to her interests in problem solving clinical trials from several different perspectives.

Her goals for SCT include to to continue to contribute to the Society from a clinician and operations perspective and to continue to grow the membership in diversity and educational opportunities.

**Denise Esserman**
**Board of Directors**
**2021-2025**

**Denise Esserman, MS, PhD** is Associate Professor of Biostatistics, Yale School of Public Health

Her primary focus in research has been on the advancement of methods for the design and analysis of pragmatic clinical trials and to train the next generation of Biostatisticians in the field of clinical trials. To this end, she developed a methodology core at the Yale Center for Analytical Science (YCAS) to address the growing methodological challenges with clinical trial design encountered at Yale and beyond. The methodology core has focused on several key areas: two-stage clinical trial designs; cluster randomized trials, including trials with complex time-to-event structures, stepped -wedge designs, hierarchical factorial designs and individually randomized group treatment trials; and the use of electronic health records to ascertain outcomes in pragmatic clinical trials.

She has been a member of the SCt Students Scholarship Committee since 2016.

Her goals for SCT are to engage and educate the next generation of clinical trialists so that we can build upon the strong foundation of SCT and continue to grow and innovate the field of clinical trials through a strong and enduring pipeline.

**Julianna Toles**
**Board of Directors**
**2021-2025**

**Juliana Tolles, MD, MHS** is Assistant Professor of Emergency Medicine at the David Geffen School of Medicine at UCLA, core emergency medicine faculty at Harbor-UCLA Medical Center in Los Angeles, and medical and statistical scientist for the statistical consulting group Berry Consultants.

Her research interests include adaptive trial design, emergency medical services, resuscitation and trauma care  She is an investigator for the Strategies to Innovate Emergency Clinical Care Trials (SIREN) network Southern California site. I have designed adaptive trials to investigate therapies in diverse clinical areas including stroke, pediatric heart disease, and cardiac arrest.

Dr. Tolles has been a member of the SCT Program Committee since 2019.

Her goals for SCT include:

To Increase the diversity of the SCT's membership

To expand the role of the SCT in shaping public and scientific discourse about the design and conduct of clinical trials

Please join us in congratulating all of our newly elected Society for Clinical Trials leaders.

# 2021 SCT Class of Fellows



**Elizabeth Thom**
**Chair,**
**Fellows Committee**

**J. Jack Lee**
**Co-Chair**
**Fellows Committee**

***SCT Fellows Committee is comprised of Elizabeth Thom (Chair)***
***J. Jack Lee (Co-Chair)***
***Raymond P. Bain***
***Christopher Coffey***
***Roger J. Lewis***
***Anne S. Lindblad***
***John David Norrie***
***Carol K. Redmond***
***Scott Rushing***

The Society for Clinical Trials Board of Directors has unanimously approved the following candidates as Fellows of the SCT . On behalf of the SCT Board of Directors and members of the Fellows Committee, please join us in congratulating the SCT Class of 2021 fellows for their extraordinary professional achievements.

**Dixie J. Ecklund, RN, BSN, MSN, MBA**
**Director of Operations**
**Clinical Trials Statistical and Data Management Center**
**Adjunct Assistant Professor, College of Nursing**
**University of Iowa, USA**

For outstanding leadership, mentorship, and management of the Clinical Trials Statistical and Data Management Center at the University of Iowa; for strong contributions to training the next generation of clinical trialists; for a career-long commitment to building and sustaining outstanding clinical trials research teams; and for dedicated service to the Society.

**Elizabeth Garrett-Mayer, PhD**
**Director, Division of Biostatistics and Research Data Governance**
**Center for Research and Analytics**
**American Society of Clinical Oncology, Alexandria, VA, USA**

For important contributions to the design and analysis of cancer clinical trials, for leadership in clinical trial coordination and conduct at the American Society of Clinical Oncology, for outstanding contribution to the education of graduate students, fellows, and residents; and for exceptional service and commitment to the Society.

**Janet Athene Lane, PhD**
**Professor, Trials Research Population Health Sciences**
**University of Bristol, UK**

For important contributions to the design and conduct of clinical trials, particularly the landmark ProtecT study; for leadership in clinical trial coordination and conduct, most recently as co-Director of Bristol Randomised Trials Collaboration, UK; for national leadership on numerous advisory committees, and for service to the Society.

**Graeme S. MacLennan. MSc, PGCE(S)**
**Director & Professor**
**The Centre for Healthcare Randomised Trials**
**University of Aberdeen, UK**

For significant contributions to the design and analysis of clinical trials, particularly the implementation of innovative design and the conduct and delivery of complex trials; for leadership in clinical trial coordination and conduct particularly in surgical trials; for national leadership on numerous Data Monitoring Committees and Trial Steering Committees, including for the National Institute for Heath Research and the Medical Research Council; and for distinguished service to the Society.

**Sumithra J Mandrekar, PhD**
**Professor of Biostatistics and Oncology, Mayo Clinic**
**Group Statistician, Alliance for Clinical Trials in Oncology**

For significant contributions to the statistical methodology for the design, conduct and analysis of clinical trials, particularly in oncology; for leadership in clinical trials and data management coordination at Mayo Clinic and the Alliance for Clinical Trials in Oncology; for leadership on national and international steering committees and advisory panels related to cancer, including the National Cancer Institute; and for distinguished service to the Society.

# SCT Selects the RECOVERY Trial as David Sackett Trial of the Year 2020

**Marc Buyse**
**Chair,**
**Trial of the Year Committee**

**Debra Condon**
**Co-Chair,**
**Trial of the Year Committee**

**SCT Trial of the Year Committee Members**

**Marc Buyse (Chair)**

**Debra Condon**

**(Co-Chair)**

**Suzanne Dahlberg**

**Dean Follmann**

**Jessica Overbey**

**Frank Rockhold**

**Yves Rosenberg**

The Society for Clinical Trials (SCT) is pleased to announce that the prestigious David Sackett Trial of the Year Award will be presented today to the RECOVERY (Randomized Evaluation of COVID-19 Therapy) trial led by the University of Oxford.

Every year since 2008, the SCT has awarded the David Sackett Trial of the Year Award to a randomized, controlled trial published in the previous calendar year that best fulfills the following standards:

> Improves the lot of humankind;
>
> Provides the basis for a substantial, beneficial change in health care;
>
> Reflects expertise in subject matter, excellence in methodology, and concern for study participants;
>
> Overcomes obstacles in implementation; and
>
> Based on the presentation of its design, execution, and results is a model of clarity and intellectual soundness.

The RECOVERY trial was a large, pragmatic randomized trial for the treatment of hospitalized patients with a suspected or confirmed COVID-19 infection. It was designed and implemented at extraordinary speed in the midst of the COVID-19 pandemic, at a time of great need for effective treatments to reduce mortality among hospitalized patients.

“The RECOVERY trial is well chosen for this year’s award and is presented on the International Clinical Trials Day,” said Dr. Susan Halabi, President of SCT and Professor of Biostatistics and Bioinformatics, Duke University. “The COVID-19 pandemic underscored the importance of responding with agility while still maintaining scientific rigor. What we're learned from the RECOVERY trial is that scientific achievements can be made expeditiously,” Halabi said. “This trial is a superb example of that; the scientific team did not sacrifice science for efficiency, and carefully planned efficiency fostered agility. The RECOVERY trial highlights the immense and positive impact that clinical trials have on the world, especially during the pandemic. Engagement of several thousands of volunteers is truly impressive.

Lastly, this trial would serve as a model for efficient design for future clinical trials for all diseases.”

“This year, the Trial of the Year Committee received several nominations for outstanding trials, including those that have arguably had the most profound impact on public health during a pandemic: the COVID-19 vaccination trials,” said Dr. Marc Buyse, Chair of the SCT Trial of the Year Committee. “Whilst all nominated trials would have deserved the award, the vote finally went to RECOVERY not just because of its spectacular speed, efficiency, and pragmatism, but also because this trial will have a lasting impact on how trials should be conducted in all disease areas going forward.”

-Peter Horby, Professor of Emerging Infectious Diseases in the Nuffield Department of Medicine, University of Oxford, and Joint Chief Investigator for the RECOVERY trial, said: “This award is a testament and a tribute to the exceptional work of many thousands of people working under the most difficult circumstances. 2020 was awful in so many ways but the RECOVERY trial was uplifting, showing what can be achieved when there is unity, resolve and a commitment to good science. RECOVERY is a truly national achievement and every person involved should feel incredibly proud. I would encourage them to regularly remind themselves that there are many thousands of people who are only alive today thanks to their efforts."

# RECOVERY Trial - David Sackett Trial of the Year 2020 (continued)

The trial, sponsored by the United Kingdom National Health Services, reduced administrative burdens to the minimum possible, tested widely available treatments, and allowed physicians to choose, among several treatments tested, those which they had access to.

Ultra-simplified trial procedures resulted in two-thirds of all patients to be randomized in some hospitals, making the RECOVERY trial the first trial to combine real-world evidence with the toss of a coin.

Treatments tested initially included lopinavir-ritonavir, two drugs used to treat HIV, dexamethasone, an anti-inflammatory drug, hydroxychloroquine, a treatment for malaria. Due to its large size, the trial could show quickly and reliably that lopinavir-ritonavir and hydroxychloroquine were ineffective, while dexamethasone reduced mortality by one-third in patients receiving invasive mechanical ventilation and by one-fifth in patients receiving oxygen.

This landmark finding changed clinical practice worldwide. The RECOVERY trial was designed as a platform trial that can drop or add treatments dynamically. The trial has randomized almost 40,000 participants today, and is still actively recruiting in more than 170 clinical sites. It is currently testing Regeneron's combination of monoclonal antibodies directed against coronavirus, colchicine, an anti- inflammatory drug, baricitinib, an immunomodulatory drug used in rheumatoid arthritis, and aspirin.

Leaders from the Trial presented the study at the Society for Clinical Trials Meeting on May 20, 2021, International Clinical Trials Day. Presenters included:

CLINICAL INTRODUCTION

PETER HORBY

PROFESSOR OF EMERGING INFECTIOUS DISEASES AND GLOBAL HEALTH

TRIAL DESIGN AND RESULTS

RICHARD HAYNES

PROFESSOR OF RENAL MEDICINE AND CLINICAL TRIALS

USE OF ROUTINE HEALTH DATA

MARION MAFHAM

CLINICAL RESEARCH FELLOW, CTSU

STATISTICAL METHODS

JONATHAN EMBERSON

PROFESSOR OF MEDICAL STATISTICS AND EPIDEMIOLOGY

QUESTIONS & ANSWERS

MARTIN LANDRAY

PROFESSOR OF MEDICINE AND EPIDEMIOLOGY

Nominations for the Trial of the Year are submitted by Society members, investigators, and interested scholars from around the world. Dr. David L. Sackett was a dedicated long-time SCT member and a pioneer in evidence-based medicine and champion of clinical trials. The Trial of the Year Selection Committee will issue a call for nominations in the Fall of 2021. Additional information and a list of past Trials of the Year on www.sctweb.org/toty.cfm.

CLINICAL TRIALS
Journal of the Society for Clinical Trials

# Highlights of Recent Issues April & June 2021

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

By Colin Begg, Editor

## April 2021

The April issue of *Clinical Trials* features some studies stimulated by experiences of running clinical trials during the COVID-19 pandemic. **James Burns** and **Ffion Carlin** discuss the logistical challenges and lessons learned from conducting multiple clinical trials in a hospital setting during the COVID-19 pandemic.

**Deborah Zarin** and **Stephen Rosenfeld** document in detail the wide variety of outcome scales used in COVID -19 trials, some with similar names, pointing to the risks of misinterpretation if results are compared or aggregated across studies.

**Michelle Meyer** and colleagues propose a 3-stage framework for prioritizing the countless COVID-19 clinical trials proposed. In work unrelated to COVID-19

**Osamu Yamada** and colleagues demonstrate that remote risk-based monitoring can work as well as on-site monitoring, saving clinical trial costs. F

inally, **Leandro Garcia Barrado** and **Tomasz Burzykowski** examine the properties of biomarker-driven outcome-adaptive randomization, showing that power losses are highly likely if the biomarker is inaccurate.

## June 2021

The leading feature of the June issue of *Clinical Trials* is the state of clinical trials in Russia. **Anastasiya Chirkova** and colleagues provide a fascinating account of how clinical trials were conducted during the Soviet era, focusing on clinical trials of Meldonium, the drug that tripped up numerous athletes including Maria Sharapova.

**Janet Wittes** provides a commentary, drawing parallels with the complexities of teaching probability theory in a society where the concept of randomness contradicted the official view of Marxist determinism.

However, **Dilyara Nurkhametova** and colleagues from the Russian Cochrane center show that modern standards for clinical trials methodology are taking root in Russia, but trial registration standards leave a lot to be desired. In other papers,

**Sharon Love** and colleagues explain carefully the distinction between data cleaning and central monitoring in clinical trials, highlighting the potential prioritization inefficiencies.

Finally, **Korbinian Brand** and colleagues have surveyed sub-group analyses in cardiovascular clinical trials showing that these are indeed more commonly reported when the primary analysis is not significant.

# SCT Awards Students from Underrepresented Groups

The newly formed SCT Equity, Diversity and Inclusion Committee selected eight students from underrepresented groups in the fields of biostatistics, statistics, epidemiology, nursing, data sciences and computer science to promote a racially and ethnically diverse SCT membership.

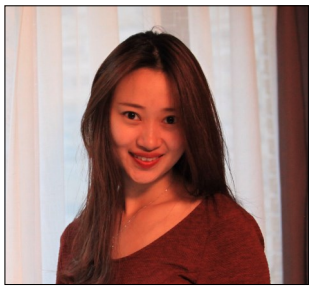
Their Registration for the Annual Meeting was sponsored by SCT. In addition, awardees were invited to attend a welcome reception with the SCT President, Chair and Members of the ED&I committee and will have an opportunity to network with SCT Leadership.

Jacqueline Aredo-Stanford University
Julia Alexis Dias-Harvard School of Public Health
Zhe Fang-Harvard T.H. Chan School of Public Health
Larissa Maini-McMaster University
Christian Pascual-University of California, San Diego
Myanca Rodriguez-McMaster University
Ella Rubio-University of California San Francisco
Donya'e Smith-University of Maryland

# Sylvan Green and Thomas Chalmers Award Winners

**Lara Philipps**

**Sylvan Green Award Winner**



**Xiaoyu Tang**

**Thomas Chalmers Award Finalist**

**Subodh Selukar**

**Thomas Chalmers Award Winner**

**Siyun Yang**

**Thomas Chalmers Award Finalist**

## Sylvan Green Award

The Society made its first Sylvan Green award in 2011 to honor the legacy of Sylvan Green, MD who served as President of the Society in 1994, Chaired the Education Committee from 1994-2001, led the Student Scholarship Committee from 2003-2008, and was named an SCT Fellow in 2007. Serving 24 years in the Biometry Branch of the National Cancer Institute, including leadership in Clinical and Diag-nostic Trials Section, Dr. Green made numerous land-mark methodology and practice contributions to clinical trials. He was a professor at Case Western Reserve Uni-versity School of Medicine from 1997 to 2002 and Pro-fessor of Epidemiology and Biostatistics - College of Pub-lic Health & inaugural Linda McCartney Breast Cancer Chair in Biometry, University of Arizona, Arizona Cancer Center from 2003 to 2008.

This year's awardee is **Dr. Lara Philipps, Institute of Cancer Research, London UK**. Dr. Philipps is undertaking a PhD at the Institute of Cancer Research in the efficient collection of toxicity data in clinical trials. Prior to commencing her PhD she has been practicing in clinical medicine for 8 years with 4 years as a clinical oncology registrar, providing her with an insight into the patient journey through treatment. The title of her talk was "Study within a trial comparing electronic versus paper patient reported outcome collection."

## Thomas Chalmers Award

The Thomas Chalmers Scholarship is named in honor of Dr. Thomas Chalmers, who was a founding member of the SCT, and served on the Board and as President in 1984. He also founded the SCT Student Scholarship Program, and the Annual Scholarship was named in his honor, to recognize his lifetime of service to the Society. Dr. Chalmers was a dedicated early advocate of randomized trials, evidence-based medicine, pioneered methods and practices that have become standards today. He held numerous education and research leadership positions including: Chief of Medical Services, Lemuel Shattuck Hospital, Boston (1955-68), Director of Clinical Center at NIH (1970-73), Dean of Mount Sinai Medical Center and School of Medicine (1873-83). He later held appointments at Harvard School of Public Health, Tufts University School of Medicine, Boston VA.

This year's Thomas Chalmers Student Scholarship Award competition again produced a large body of outstanding submissions spanning many important and timely areas of clinical trials. The three Chalmers Award finalists, presented their work at a special session at the 2021 SCT Virtual Annual Meeting.

**Subodh Selukar** is a fifth-year PhD student at the University of Washington's Department of Biostatistics, and his dissertation concerns practical considerations for issues in modern clinical trials across trial design, conduct and analysis. In particular, he has proposed a novel method for studying cure model appropriateness in studies with long-term survivors and is developing a framework for appropriately conducting N-of-1 trials with sequential monitoring and jointly analyzing a series of sequentially monitored N-of-1 trials. At the 2021 Annual Meeting, he presented a third project in which he extended existing methods for stratified randomization in order to account for differing experimental arm eligibility in platform trials.

**Xiaoyu Tang** is a Ph.D candidate in the Department of Biostatistics at Boston University School of Public Health. She obtained her bachelor's degree in Mathematics at Boston University and received her master's degree in Statistics at Yale University. She worked on Quality Assurance process in Phase 3 clinical trials at Vertex Pharmaceuticals before. Her

ongoing research is to develop novel evidence-synthesis models to evaluate treatment effects and to validate surrogate endpoints using different measures of treatment effects in clinical trials with time-to event outcomes. Her research interests also include evaluating addiction and substance use disorder interventions. The title of her talk was “Bayesian multivariate network meta-analysis model for the difference in restricted mean survival times”.

**Siyun Yang** is a third year PhD candidate at Duke University Department of Biostatistics and Bioinformatics. Her main research interests are causal inference and cluster randomized experiments. Before PhD training, she collaborated with an interdisciplinary network of investigators conducting research at Duke, by providing expertise in study design and quantitative methodology. Her talk was titled “Covariate adjustment in subgroup analyses of randomized clinical trials: A propensity score approach.”

Following superb presentations by all finalists in an invited session at the SCT meeting, the winner of the Chalmers award was **Sukodh Solukar**. Congratulations to all of them for their great work.

## Sylvan Green and Thomas Chalmers Award Winners (continued)

**Elizabeth Garrett-Mayer**
**Chair, Student Scholarship Committee**

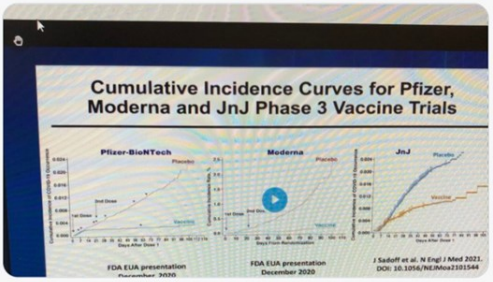
**Cody Chizuan**
**Co-Chair**
**Student Scholarship Committee**

# Tweets from the 2021 Meeting

**Cory E. Goldstein** @coryegoldstein · May 17
The Society for Clinical Trials #SCT2021 annual conference has begun! Looking forward to many sessions, including one in ~15 minutes on the Ethics and Future of Human Challenge Trials with @SeemaKShah, @charlesweijer and others @SCTorg

**Jen Gassman** @JenniferGassman · May 17
Society for Clinical Trials @SCTorg Conference #SCT2021 Come to virtual Session 16 1-2pm Weds & hear how we'll show at the start of our surgical RCT how we can enroll 3900 patients on an R01 budget. As a bonus, see how many words & slides I managed to fit in 10 minutes exactly

**Mithat Gönen** @gonen_mithat · May 17
Three COVID-19 success stories. From Cliff Lane's #SCT2021 Founders Lecture. @SCTorg

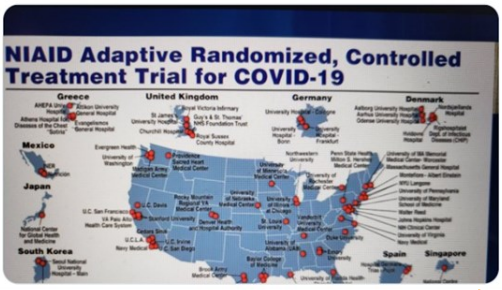



**SCTorg** @SCTorg · May 18
Get excited for the upcoming DMC Registry! Dave DeMets is discussing it right now. #SCT2021


SCTorg Retweeted
**Suzanne Dahlberg** @SuzDahlberg · May 20
100% true! Also true: I should have been encouraged to join @SCTorg much earlier in my career. Don't miss out!

**Mithat Gönen** @gonen_mithat · May 20
Today is #InternationalClinicalTrialsDay. Clinical Trials are hugely important for medical science and for public health. @SCTorg is your best resource if you want to advance your knowledge of clinical trials.

**SCTorg** @SCTorg · May 19
Come see talks about the design and implementation of clinical trials during #COVID19. #SCT2021




SCTorg Retweeted
**Katie Mellor** @katiejmellor · May 17
Nice milestone met today - first presentation of some of my DPhil research at #SCT2021

# Recently Posted Notices & Guidance Documents

- 5/20/2021 - Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products: Draft Guidance for Industry
- 5/17/2021 - COVID-19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention: Guidance for Industry
- 5/11/2021 - E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials: Guidance for Industry
- 04/28/2021 FDA Takes Action For Failure to Submit Required Clinical Trial Results Information to ClinicalTrials.Gov

Being transparent about the results of completed clinical trials enables important advances in the development of medical products and helps ensure a safe, effective and efficient clinical research enterprise. Across all types of medical product trials, the U.S. Food and Drug Administration works with responsible parties to encourage compliance with the requirements to submit registration and summary results information to the ClinicalTrials.gov data bank, managed by the National Institutes of Health (NIH)/National Library of Medicine.

Sponsors of clinical trials may represent a variety of organizations, including academic institutions, hospitals, private companies and government research organizations, or could be individual researchers. Federal law requires that responsible parties, typically trial sponsors, register applicable clinical trials on ClinicalTrials.gov within 21 days after the first human subject is enrolled and submit certain summary results information for those trials, generally no later than one year after the study's completion date unless a deadline extension is obtained…. (read more)

- 04/29/2021 FDA Authorizes Marketing of First Device that Uses Artificial Intelligence to Help Detect Potential Signs of Colon Cancer
- 03/19/2021 Coronavirus (COVID-19) Update: FDA Authorizes First Machine Learning-Based Screening Device to Identify Certain Biomarkers That May Indicate COVID-19 Infection
- 2/22/2021 - Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID 19 Public Health Emergency
- 2/22/2021 - Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry
- 2/22/2021 - Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests: Guidance for Test Developers and Food and Drug Administration Staff
- 2/11/2021 - Investigational COVID-19 Convalescent Plasma: Guidance for Industry
- 01/12/2021—FDA Releases Artificial Intelligence/Machine Learning Action Plan
- 01/04/2021—FDA Takes Steps to Provide Clarity on Developing New Drug Products in the Age of Individualized Medicine

Advances in scientific knowledge and drug development technology have provided an opportunity for new approaches to drug development, including the development of drugs for the treatment of rare diseases. These advances have contributed to an increase in development and approval of drugs for the treatment of rare diseases in recent years. In fact, in the past eight years, the U.S. Food and Drug Administration has approved more than twice as many drugs for rare diseases, often referred to as orphan drugs, as in the previous eight years.
For genetic diseases, recent approaches to testing and molecular diagnosis have allowed us to pinpoint, in some cases, the exact cause of a patient's disease. For a patient with a very rare genetic disease… (read more)

# Clinical Trials News & Announcements from the Clinical Trials Transformation Initiative

## Executive Think Tank Meeting Held with Data and Tech Community

On April 8, CTTI convened an Executive Think Tank Meeting with leaders from over 20 data and technology organizations, as well as representatives from FDA. During the meeting, we heard from data and tech companies on their thoughts for meaningful partnership with the CTTI community to achieve the Transforming Trials 2030 vision. The valuable feedback from this meeting will be used to inform CTTI's strategy for strengthening engagement with the data and technology community. A summary of the themes and suggested next steps will be shared at the upcoming Member Meeting.

## Building Better Clinical Trials: A Case Study Exchange (CSE)

Last month, CTTI released Building Better Clinical Trials: A Case Study Exchange (CSE), a new resource that features case studies from more than 30 organizations that have used CTTI recommendations or tools to improve clinical trials. The CSE is a forum where organizations can share best practices, examples, and lessons learned with each other. It is also a way to demonstrate the use and impact of CTTI's work. Please contact Karisa Merrill, strategy and engagement project manager, if you have a potential case study to add.

## Draft Principles of ICH E6 Good Clinical Practice (GCP) now available

Acknowledging the wide and substantial impact of ICH E6, the ICH Management Committee is making available a draft, work-in-progress version of the updated principles that are currently under development by the ICH E6(R3) Expert Working Group (EWG). Although the EWG's work is continuing and the group is still progressing towards Step 2 of the ICH development process, the ICH Management Committee decided that sharing the draft version of the principles would facilitate transparency and common understanding. Once the updated ICH E6 Guideline achieves Step 2 of the ICH guidance development process, public input will be invited and considered. Additionally, the E6(R3) EWG will organize, on 18-19 May 2021, a global web conference to present the current draft of the GCP principles as a work in progress, with further details to be announced shortly.

## FDA Leverages Real-World Evidence

Advances in the availability of real-world data (RWD) sources – such as electronic health records, registries, medical claims, pharmacy data and feedback from wearables and mobile technology – have increased the potential to generate robust real-world evidence (RWE), to support FDA regulatory decisions. The FDA has published examples of how RWE is being used in medical device regulatory decisions for the Center for Devices and Radiological Health (CDRH).

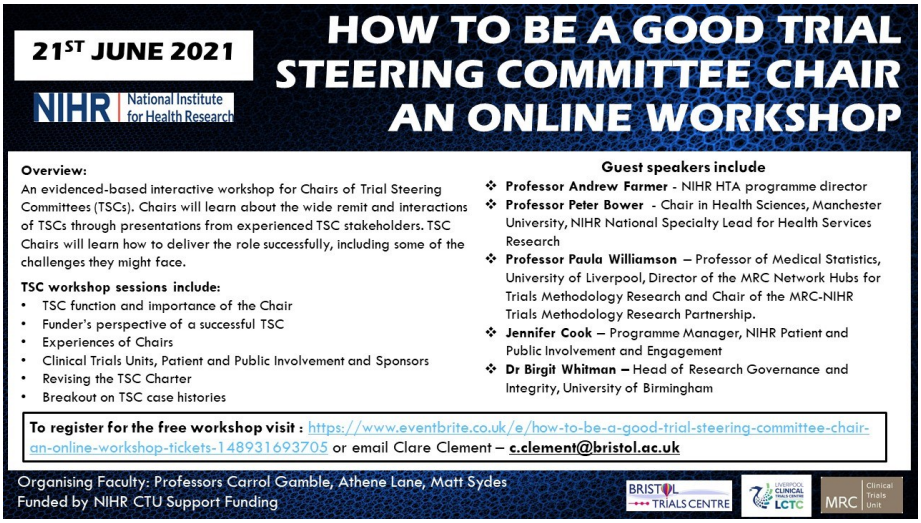
## FDA's Data Modernization Action Plan

In 2019, the FDA released the Technology Modernization Action Plan (TMAP). The follow up document, Data Modernization Action Plan (DMAP), proposes a framework and actionable recommendations for FDA's Data Strategy. Its 3 key components are identifying and executing high value driver projects for individual centers and for the Agency; developing consistent and repeatable data practices across the Agency; and creating and sustaining a strong talent network combining internal strengths with key external partnerships.

## CTTI Publication on Investigator Experiences Using Mobile Technology

A new manuscript, published in JMIR mHealth and uHealth, highlights CTTI's work done in the Engaging Patients and Sites project, revealing key investigators' preferences and barriers to incorporating digital technologies into clinical research. Congratulations and thank you to the co-authors! For more information, please contact project manager Zach Hallinan.






**Register here**

## Essentials of Clinical Trials

The Medical Statistics Department (MSD) at the London School of Hygiene & Tropical Medicine (LSHTM) will be running an online short course in clinical trials.

This course gives attendees a clear understanding of the fundamental principles of Randomised Clinical Trials (RCTs). Video lectures and live online Q&A and practical sessions will cover the key issues in design, conduct, analysis and reporting, with a focus on major clinical trials that directly influence clinical practice. Topics are addressed with perspectives from both public sector research and the pharmaceutical industry.

The course is relevant to anyone who'd like to get an understanding of the rigorous evaluation of interventions in health care, including clinical research professionals, research managers, statisticians and other scientists with an interest in clinical trials.

Places on the course are limited.

The course runs for 5 days from 5 to 9 July 2021.

*The in-person version of this course has previously been approved by the Federation of the Royal Colleges of Physicians of the United Kingdom for up to 30 category 1 (external) CPD credit(s). We are anticipating we will have the same accreditation for the course in the online setting.*

For further information and an application form please visit: https://www.lshtm.ac.uk/study/courses/short-courses/clinical-trials

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The Jaeb Center for Health Research was established in 1993 as a freestanding, nonprofit coordinating center for multi-center clinical trials and epidemiologic research. The Jaeb Center's focus is eye disorders or type 1 diabetes.

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## UNIVERSITY OF WISCONSIN DCC

The Data Coordinating Center (DCC) is a component of the Clinical Trials Program in the Department of Biostatistics and Medical Informatics at the UW School of Medicine and Public Health. The DCC supports investigator-initiated NIH or industry-sponsored RCTs. We provide expertise in planning, conduct, monitoring, and analysis of clinical trials.

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# Save the Dates - Upcoming SCT Annual Meetings

**43rd Annual Meeting**

**May 15-18, 2022**

**San Diego, California**

**USA**


**44th Annual Meeting**

**May 21-24, 2023**

**Baltimore, MD**

**USA**

# Information About

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Executive Committee (2021-2022)

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Lehana Thabane (President-Elect)
Susan Halabi (Past-President)
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| | |
|---|---|
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| | Toshimitsu Hamasaki (Co-Chair) |
| Education: | Michael Grayling (Chair) |
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