



VOLUME 34, #4

NEWSLETTER

APRIL 2023

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SCT President's Column



**Lehana Thabane
President 2022-2023**

Thank You for Your Long Service to the Society for Clinical Trials

I want to personally express my appreciation and gratitude to all members who continue to make the Society for Clinical Trials the best Society to be part of. In particular, a huge thank you to all the long-term members of the Society; many who continue to contribute their talents and skills to its functions and operations including serving as leaders and committee members. Below we recognize them for their long membership and service to SCT:

40+ Years

- Michael Kris
- Marie Diener-West
- Barry Davis
- Elizabeth Wright
- James Herndon
- Virginia Howard
- Jeannette Lee
- Kenneth Schechtman
- Stan Shapiro
- Gary Johnson
- Jonas Ellenberg
- Peter Peduzzi
- Frank Rockhold
- John Lachin
- Barbara Hawkins
- David DeMets
- Philip Prorok
- Jay Herson
- Dennis Dixon
- Domenic Reda
- Mae Gordon
- Susan Ellenberg

30+ Years

- J. Jack Lee
- Richard Goldstein
- Robert Edson
- Anne Lindblad
- Edward Lakatos
- J. Terrell Hoffeld
- James Neaton
- Jeff Doerzbacher
- Wasima Rida
- Colin Begg
- Paula Roberson
- KyungMann Kim
- Roy Beck
- Raymond Bain
- Gerald Beck

20+ Years

- Ivan Chan
- Marc Schwartz
- Masha Kocherginsky
- Judith Bliss
- Wei-Ting Hwang
- Leslie McClure
- Elaine Pascoe
- Judith Bechuk
- Lehana Thabane
- Sheila Sprague
- Susan Halabi
- J. Michael Dean
- Satoshi Teramukai
- John Evans
- Kirk Easley
- Katherine Guthrie
- Douglass Chapman
- Yutaka Matsuyama
- Marc Walton
- Marion Campbell
- Janelle Rhorer

SCT President's Column

20+ Years

- Toshimitsu Hamasaki
- Johnathan Smith
- Simon Day
- Lisa Jones-Jordan
- Richard Gelber
- Scott Evans
- Daniel Heitjan
- Susan Groshen
- Neil Bressler
- Nicole Close
- Michele Melia
- James Torner
- Stephen George
- Steve Belle

10+ Years

- Dietrich Haubenberger
- Larisa Tereshchenko
- Robert Annechiarico
- Jose-Miguel Yamal
- Amber Salter
- Theodore Lystig
- Jordan Elm
- Joseph Koopmeiners
- Donna Levy
- Barbara Braffett
- Sonia Thomas
- Scott Keith
- Kurt Olson
- Edward Korn
- Chen Hu
- Dario Gregori
- Tracy Bergemann
- Sameer Parpia
- Siobhan Brown

- Andrea Troxel
- Abigail Shoben
- Kieran O'Brien
- Laura Smeaton
- William Meurer
- Kent Koprowicz
- Cody Chiuzan
- Judith Goldberg
- Pamela Tenaerts
- Sean Devlin
- Trevis Huff
- Cristina Murray-Krezan
- O. Williams
- Steven Snapinn
- Martin Stockler
- Kyle Rudser
- Wendy London
- Shaji Kumar
- Walter Ambrosius
- Stephanie Pugh
- Haruko Yamamoto
- Lukas Makris
- Stefan Michiels
- Qiang Zhang
- Stephen Bernard
- Tim Friede
- Emily Dressler
- Susan Murphy
- Jody Ciolino
- Kaleab Abebe
- Thomas Cook
- Robert Lindblad
- Heidi Weiss
- Lynda Emel
- Paul VanVeldhuisen
- Roger Lewis

- Tony Panzarella
- Sumithra Mandrekar
- Emma Hall
- Joan Reisch
- Dixie Ecklund
- Joan Chmiel
- Qian Shi
- Eleanor Schron
- Sharon Yeatts
- Myeong Soo Lee
- Nancy Silliman
- Li Chen
- Bruce Levin
- Theodore Karrison
- Mithat Gönen
- Yves Rosenberg
- Deborah Donnell
- Peter Jaehnig
- Yu Shyr
- Zhiying You
- Joseph Rausch
- Michelle Walter
- Dean Fergusson
- Jeff Szychowski
- Charity Patterson
- Karla Ballman
- Laurent Billot
- Letitia Perdue
- Songthip Ounpraseuth
- Mei-Chiung Shih
- Xian-Jin Xie
- David Couper
- Abhik Das
- Christopher Coffey
- Sharina Person
- Valerie Durkalski

Thank you for your loyalty and commitment to the SCT. I look forward to seeing you all in Baltimore next month!

Lehana Thabane

Lehana Thabane,

SCT President

This list is based on those who are active members with paid memberships as of April 10, 2023. If you're not on this list and believe you should be, please email contact@sctweb.org.

Save the Date
44th Annual Meeting of the Society for Clinical Trials
**The meeting theme is: “Championing High-quality Evidence
to Optimize Human Health.”**
May 21-24, 2023
Baltimore Marriott Waterfront
Baltimore, MD

The SCT 2023 Member Volunteer Portal is Still Open!

SCT Volunteers are the heart of our professional society. Your skills, talents and perspectives are welcomed to continue to build a strong, energetic and dynamic society. Submit your interest in the volunteer portal at sctweb.org by May 31st.



Curtis Meinart Keynote Speaker

Dr. John Ioannidis

Professor of Medicine (Stanford Prevention Medicine),
of Epidemiology and Population Health and By Courte-
sy, of Statistics and of Biomedical Data Science at
Stanford University



Founders Lecture Keynote Speaker

Dr. Kirsten Bibbins-Domingo

Editor-In-Chief, JAMA (Journal of the American Medical
Association) and the JAMA Network, and Professor,
Epidemiology & Biostatistics and Medicine at the Uni-
versity of California, San Francisco

CLINICAL TRIALS

Journal of the Society for Clinical Trials



By Colin Begg, Editor

April, 2023 Issue Highlights

The **April** issue of *Clinical Trials* features two papers on the methodology of cluster randomized trials. **James Martin** and colleagues examine the adaptation of “minimization” to ensure covariate balance in this context. Partially clustered clinical trials are those with both individual and clustered data. **Kylie Lange** and colleagues provide a framework for defining these trial designs, including proposed terminology. The April issue also features two papers run-in periods for trials. **Lingyun Ji** and **Todd Alonzo** consider the design of the safety run-in period for

phase II trials in pediatric oncology, offering some design strategies. **Gosuke Homma** and **Takashi Daimon** investigate the FDA recommended placebo lead-in design in the context of a binary outcome, showing that its appropriateness depends on key parameters. As always the journal welcomes submissions from SCT members.

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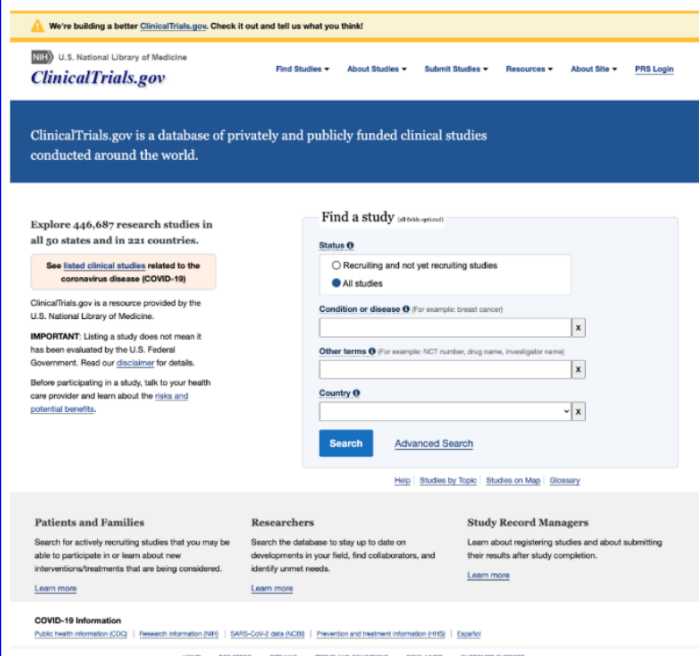
[@clintrialsj](https://twitter.com/clintrialsj) to keep up to date with the latest from the journal.



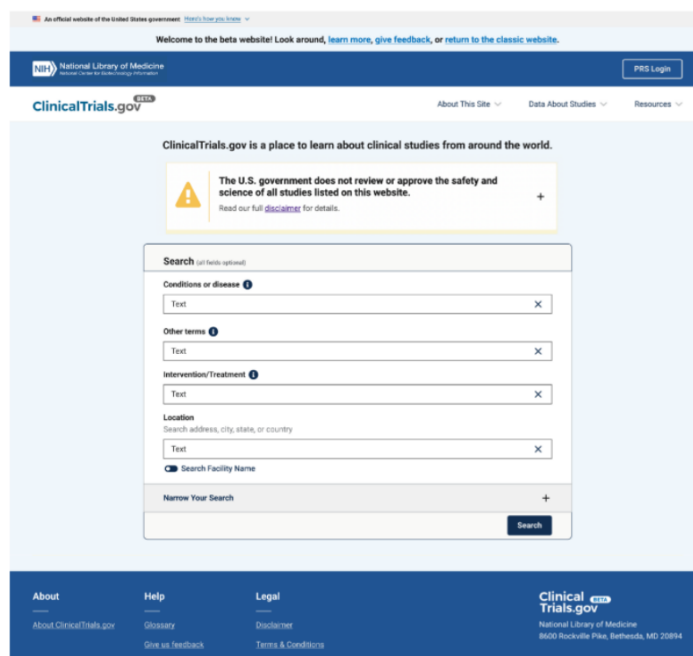
ClinicalTrials.gov is Modernizing to Serve You Better

Adapted from the [NIH website](#), originally by Anna Fine

In June 2023, we will reach an important milestone: replacing the current website with the modernized ClinicalTrials.gov website. This modernized site will implement the innovations we have designed based on user feedback, including an updated look and feel and improved functionality for searching, viewing, and downloading information about clinical trials.



The current ClinicalTrials.gov website.



The beta ClinicalTrials.gov website, with added features and functionality based on user feedback.

The Robert A. Winn Diversity in Clinical Trials: Career Development Award application is now open!



Award amount

\$120K/year for 2 years; funding is to protect 40% of Scholars' work time for program participation

Eligibility

- Must identify as a racial/ethnic group designated as "underrepresented in medicine" OR have a demonstrated commitment to increasing diverse patient participation in clinical trials, see website for specific ethnicities.
- Must be a US Citizen, Lawful Permanent Resident, or hold a H-1B or O-1 Visa
- Must hold the degree of MD, MD/PhD, DO, or DO/PhD
- Must focus on one of the following clinical research areas: cancer (hematology and oncology), cardiovascular disease or immunologic disorders
- Must be an Early-Stage Investigator (ESI)

Deadline to apply

May 12, 2023

Program goal: To transform the clinical research landscape by building and strengthening partnerships between clinical investigators and the communities where their patients reside, with a goal of ultimately engaging a patient population that mirrors the epidemiology of the disease studied.

Robert A. Winn Diversity in Clinical Trials: Community-oriented Clinical Trialist Training (Winn COCT Training)

To train a new generation of world class clinical trialists who possess the additional knowledge and competencies to foster active community engagement in clinical and translational research.

Winn-AACR DICT workshop (5 ½ days)

- Education sessions/core curriculum
- Breakout sessions
- On-demand sessions
- Clinical trial development sessions
- Faculty mentoring sessions

Winn COCT curriculum (2-years)

- Scholars forum
- Community engagement activities
- Capstone project
- Annual convenings
- Individual professional development plans



**ROBERT A. WINN
DIVERSITY
IN CLINICAL TRIALS
AWARD PROGRAM**

Established by the Bristol Myers Squibb Foundation

**Scan the code below to apply
for the Robert A. Winn Diversity
in Clinical Trials Award Program!**



To learn more, please visit the Winn Awards website for more details: diversityinclinicaltrials.org

Transforming Cancer Clinical Trials for Better, Faster Results

Adapted from [cancer.gov](https://www.cancer.gov), originally by Ben Colmery

In this Q&A, NCI Director Monica Bertagnolli, M.D., and Deputy Director for Clinical and Translational Research James H. Doroshow, M.D., talk about the challenges of clinical trials and important steps NCI is taking to improve their effectiveness.

What are the major challenges in cancer clinical trials today?

Dr. Bertagnolli: We just don't have enough people participating. Only a small percentage of people with cancer or at risk for cancer participate in clinical trials today, which greatly limits our capacity to evaluate new interventions.

Dr. Doroshow: The COVID-19 pandemic greatly exacerbated this problem. We saw a significant drop in clinical trials accrual in 2020, the first year of the pandemic. Even if we get back to where we were before the pandemic, we would still be nowhere near the accrual levels we need to make rapid progress.

Dr. Bertagnolli: Clinical trials just aren't an option for many people when they have to travel long distances and take time off of work to participate. Another big issue is that the criteria to enroll are often overly restrictive, meaning that very few of the people who might benefit once an intervention is proven effective are actually eligible to enroll.

What steps is NCI taking to improve cancer clinical trials?

Dr. Doroshow: We determined that we could develop flexible, faster, simpler, less expensive, and higher impact clinical trials by focusing on four key areas: streamlining processes for trial design and execution, focusing on essential endpoints, setting up trials in a way that broadens rather than limits participant access, and increasing efficiency of data collection.

A perfect example of how we're putting these insights into action is the S2302 Pragmatica-Lung Study, which we recently launched through NCTN. In this trial, the idea is to only collect the data that are absolutely needed to answer a straightforward question: For some people with non-small cell lung cancer, is a combination of the targeted therapy ramucirumab (Cyramza) and the immunotherapy drug pembrolizumab (Keytruda) better at prolonging life than current standard therapies?

Read more at the [NCI website](https://www.cancer.gov)

Request for Information on the NIH Office of Disease Prevention Strategic Plan for FY2024-2028

This Request for Information (RFI) is seeking feedback on the NIH Office of Disease Prevention (ODP) draft strategic plan for Fiscal Years 2024–2028 (FY24–28). The final ODP FY24–28 Strategic Plan, Prevention Research: Creating a Healthier Future for All, will outline activities coordinated by the office to assess, facilitate, and stimulate prevention research, and disseminate the results of this research to improve public health.

Weigh in at the [NIH website](https://www.nih.gov)

Interested in Presenting an SCT Webinar?

We encourage all SCT members interested in sharing their knowledge and expertise on a particular topic to submit a Webinar Proposal Form for the SCT Education Committee's review and consideration. To access the SCT Sponsored Webinar Proposal Form, go to <https://www.sctweb.org>, click on the Member Sign-In button and log in. On the Members-Only Area Home page, click on "Propose a SCT Webinar!" in the menu on the righthand side of the screen. Complete and return the Webinar Proposal Form to contact@sctweb.org. We look forward to receiving your proposal!

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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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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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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



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



45th Annual Meeting
May 19-22, 2024
Boston, MA



46th Annual Meeting
May 18-21, 2025
Vancouver, BC, Canada

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Advisor to Executive Committee:

Domenic Reda

Newsletter Editors: I-Hsin Lin,
 Lee McDaniel

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