

Contact: Kevin Bragaw

Title: Executive Director, Society for Clinical Trials

E-mail: kevinbragaw@sctweb.org **Phone:** 847-725-2286

For Immediate Release

TOGETHER trial named David Sackett Trial of the Year 2021

Arlington Heights, Ill., April 22, 2022 -- The Society for Clinical Trials (SCT) is pleased to announce that the prestigious David Sackett Trial of the Year Award will be presented to The TOGETHER Trial: An Adaptive Platform International Trial.

The award will be presented on May 16, 2022, as part of SCT's 43rd Annual Meeting, "Informing Public Health Policy with Compelling Evidence," May 15 – 18, 2022 at the Hilton San Diego Bayfront Hotel. Accepting the award and presenting the trial will be Co-Principal Investigators, Drs. Edward J. Mills, Professor, Department of Health Research Methods, Evidence & Impact, Faculty of Health Sciences from McMaster University; and Gilmar Reis, Associate Professor of Medicine, Pontifca Universidade Catolica de Minas Gerais.

Since 2008, 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 TOGETHER Trial winning nomination is based on two of the trials: Effect of Early Treatment With Hydroxychloroquine or Lopinavir and Ritonavir on Risk of Hospitalization Among Patients With COVID-19; and The TOGETHER Randomized Clinical Trial and Effect of Early Treatment With Flvoxamine on Risk of Emergency Care and Hospitalization Among Patients with COVID-19.

The overarching objective of this study is to test the hypothesis that repurposed drugs versus placebo effectively prevent worsening of COVID-19 requiring extended emergency room observation or hospitalization among high-risk adults at 28 days post-randomization. This trial is now expanding to South Africa, Pakistan, Rwanda, DRC, and Vietnam.

According to the nomination submitted by Drs. Mills and Reis, the TOGETHER Trial is now the largest placebo-controlled clinical trial for the evaluation of COVID-19 therapeutics in the world. The trial recruited its first patient on June 2, 2020 and to date has enrolled more than 5,000 patients in community-based settings, whose data have contributed to the evaluations of 11 different potentially life-saving therapeutic interventions.

-more-

The TOGETHER Trial Consortia consists of representatives from a diverse spectrum of global and national institutions, including academic, professional membership, industry and private sector, multinational, and philanthropic agencies.

“The SCT David Sackett Trial of the Year Committee was delighted to receive an enthusiastic response this year. Global trial nominations ranged from neonatal to adults and settings including Stroke, Surgical Wound Care, Ventilation Sedation, Low Birth Weight, Neonatal Hyperthermia, Addictive Disorder Use Treatment, Covid-19 Treatment, Concomitant Prophylactic Vaccinations, Tuberculosis Treatment, and Research Participation Incentivization,” said Ms. Debra Hill, MSN, RN, CCRP; Chair of the SCT Trial of the Year Committee. “I look forward to the in-person SCT Annual Meeting and learning more in depth details of the TOGETHER Trial in addition to anticipating an engaging question and answer session.”

Nominations for the Trial of the Year are submitted by Society members, investigators, and interested scholars from around the world. The 2021 Trial of the Year selection committee included: Debra Hill, Chair; Suzanne Dahlberg, Co-Chair; Andrew Cook; Manohara Basoor Halasiddappa; Yan Lin; Theodore Lystig; Jessica Overbey; and Sameer Parpia. 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 this fall. Additional information and a list of past Trials of the Year on <https://www.sctweb.org/toty.cfm>.

###

About the Society for Clinical Trials: *The Society for Clinical Trials, created in 1978, is an international professional organization dedicated to the development and dissemination of knowledge about the design, conduct, analyses, and reporting of government and industry-sponsored clinical trials and related health care research methodologies. Visit www.sctweb.org.*