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UNDER EMBARGO UNTIL MAY 20, 2021, 10:00 am EDT

### **RECOVERY trial named David Sackett Trial of the Year 2020**

Arlington Heights, Ill., May 20, 2021 -- 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’ve 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.”

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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."

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.

Nominations for the Trial of the Year are submitted by Society members, investigators, and interested scholars from around the world. The 2020 Trial of the Year selection committee included Marc Buyse (Chair), Debra Condon (Co-Chair), Suzanne Dahlberg, Dean Follmann, Jessica Overbey, Frank Rockhold, and Yves Rosenberg. 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](http://www.sctweb.org/toty.cfm).

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***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](http://www.sctweb.org).*