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Cardiac Surgeons Lead Critical COVID-19 Research Network Answers Call to Be ‘Good Citizens’ During Public Health Emergency

CHICAGO (April 14, 2021) — After dramatically changing its scope of work and mobilizing resources in record time, the Cardiothoracic Surgical Trials Network (CTSN) became a major contributor to life-changing COVID-19 research and has been recognized as the gold standard for performance across all of the National Institutes of Health (NIH)-sponsored research networks.

“The performance of the Network has been spectacular,” said Peter K. Smith, MD, a CTSN principal investigator from Duke University in Durham, North Carolina. “We’ve shown that we can make a major contribution to a national effort that’s much larger than just cardiothoracic surgery.”

Since its establishment approximately 15 years ago through a collaboration with the National, Heart, Lung, and Blood Institute (NHLBI), National Institute of Neurological Disorders and Stroke, and the Canadian Institutes for Health Research, CTSN has been involved in research that addresses evidence gaps and answers meaningful questions in cardiac surgery. With the enrollment of more than 2,000 patients in randomized trials and more than 14,000 patients in observational studies over the years, CTSN is among the top performers of NHLBI- and NIH-funded research groups.

The onset of the pandemic and the related public health emergency in early 2020 presented an opportunity for the Network to expand its focus beyond cardiac surgery and help design and execute COVID-19 studies.

A corporation known for its off-the-shelf cellular medicines approached CTSN, inviting researchers to help evaluate a cell therapy product and see if it could counteract inflammatory conditions related to COVID-19. A trial was designed in just 2 weeks; the results of that trial—conducted from April to September 2020—have not yet been published.

“It has been an immensely gratifying experience to be able to mobilize resources so quickly and address the scourge that has overtaken the world,” said Annetine C. Gelijns, PhD, a leader in the CTSN Data and Clinical Coordinating Center and also co-director of the International Center for Health Outcomes and Innovation Research at Mount Sinai in New York, New York. “We have been humbled by the generosity of all investigators and coordinators of the Network, who have come together in their selfless efforts to care for patients and advance science.”

Operation Warp Speed

Operation Warp Speed came along shortly thereafter. This program was initiated by the US government to facilitate and accelerate the testing, supply, development, and distribution of safe and effective COVID-19 vaccines, therapeutics, and diagnostics.

Several Operation Warp Speed trials—all backed by the NIH, National Institute of Allergy and Infectious Diseases (NIAID), and NHLBI—were planned to study a number of topics, including the safety and effectiveness of different therapies such as the use of monoclonal antibodies for the treatment of COVID-19 in patients who had been hospitalized. Operation Warp Speed also coordinated with existing efforts such as the NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership.

“The NIH asked us to step up as good citizens and become involved in the Operation Warp Speed COVID research trials, even though that wasn't part of our core mission,” said Michael J. Mack, MD, a CTSN principal investigator from Baylor Scott & White Health in Plano, Texas. “Not only did we step up, but we did so in an extremely short period of time. That bespoke the value of having a ready-made infrastructure of sites that was experienced with conducting research.”

According to CTSN Program Director Marissa A. Miller, who also is chief of the Advanced Technologies and Surgery Branch at NHLBI, the shift to these critical COVID-19 trials was transformative and elevated the Network “beyond a recognized trial platform within NHLBI to a national resource supporting the collective mission of the ACTIV enterprise.”

CTSN was involved in three Operation Warp Speed trials and, notably, of the five networks that participated in these studies, CTSN consistently was the highest enroller of patients, providing at least half of the total number of participants in each trial (50%, 59%, and 67%). In recognition of its substantial involvement, CTSN received a congratulatory letter from NIH Director Francis S. Collins, MD, PhD.

Results from one of the trials—on the monoclonal antibody therapy bamlanivimab—were published in *The New England Journal of Medicine* in December 2020.

Origin of CTSN

The idea to form CTSN originally was conceived in 2004 after NHLBI challenged a working group of cardiac surgeons to assess the state of cardiac surgery research, identify critical gaps in current knowledge, and determine areas of opportunity. “The most exciting part of the growth of the Cardiothoracic Surgical Trials Network and the ensuing work was helping a disparate group of investigators and site teams come together as a cohesive whole and answer the most important questions in cardiac surgical practice,” said Miller. “In this process, which was slow and challenging, the Network became a powerful clinical trial platform.”

Since its inception in 2007, CTSN has grown to 95 sites (60 in the US and 35 in Europe and South America) and been involved in approximately 20 trials—which is significant, considering the length of each trial from start to finish averages 3 to 7 years.

Future Plans for CTSN

Described by Dr. Mack as an “inclusive, not exclusive” network, CTSN always is looking to expand and welcome additional sites (US and international) that serve underrepresented patient populations and young investigators who have special interests in diversity, inclusion, and health care disparities.

In addition to expanding the network, Dr. Mack would like to see CTSN enroll more patients, more quickly, in larger trials with longer-term follow up.

“We want to be bigger, better, faster, stronger,” he said.

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For more information, contact Jennifer Bagley, Senior Media Relations Manager, at 312-202-5865 or jbagley@sts.org.

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,700 cardiothoracic surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The Society’s mission is to advance cardiothoracic surgeons’ delivery of the highest quality patient care through collaboration, education, research, and advocacy.

A list of CTSN participants is available at ctsurgerynet.org/participants.html.