Research Amidst the Pandemic

Howard A. Burris III, MD¹

Abstract

Cancer patients need access to promising investigational therapies, available only through clinical trials, and the emergence of COVID-19 and the resulting pandemic became an emerging threat to fulfilling that need. Many academic medical centers were pausing their clinical research programs, diverting their resources and sheltering their teams. Sarah Cannon, the Cancer Institute of HCA Healthcare, made the decision to stay safe, but stay the course. We knew providing these therapies, often personalized to their tumor’s molecular profile, was essential to cancer patients.

In fact, during the months of April and May 2020, Sarah Cannon’s trial enrollments actually increased as other cancer centers closed and patients were referred to our programs from all over the country. Pharma and biotech were informed of the precautions undertaken, and were largely supportive and appreciative as we kept our patients and colleagues safe. Some of the steps taken included partnering with our sites to provide telehealth appointments and reduce in-person visits, working with sponsors and regulators to allow patients to obtain labs and scans closer to where they live. The infrastructure and the power of Sarah Cannon’s community-based network was on display for cancer researchers everywhere.

Investments in information technology and digital platforms paid off handsomely during the crisis. Examples of the successes included e-consent, enabling informed consent between research nurses and patients who were in the safety of their homes, as well as remote monitoring and data capture for sponsors and contract research organizations (CROs), allowing studies to proceed safely and on time. These advanced processes and safety precautions resulted in Sarah Cannon initiating over 40 first-in-human cancer trials and a total of 200+ cancer clinical trials during 2020. These studies included several one-of-a-kind targeted agents for rare mutations, novel cellular and immunotherapy approaches, and personalized cancer vaccines, as well as continuing the ground-breaking work on the CRISPR gene editing technology for sickle cell anemia.

HCA Healthcare Research Institute (HRI) is a recently formed entity designed to expand research opportunities across our markets in a variety of diseases and specialties while utilizing the operational infrastructure of the Sarah Cannon Research Institute. With the emergence of COVID-19, HRI was the appropriate center to coordinate, implement, and support the various clinical trials needed to study this lethal virus. Under the executive leadership of

Author affiliations are listed at the end of this article.

Correspondence to: Howard A. Burris, III, MD
President of Clinical Operations
Chief Medical Officer
Sarah Cannon
1100 Dr. Martin L. King Jr. Blvd, Suite 800
Nashville, TN 37203
(Howard.Burris@SarahCannon.com)

Keywords
SARS-CoV-2; COVID-19; pandemics; biomedical research; neoplasms; clinical trials as topic; telemedicine

1 HCA Healthcare Research Institute (HRI) is a recently formed entity designed to expand research opportunities across our markets in a variety of diseases and specialties while utilizing the operational infrastructure of the Sarah Cannon Research Institute. With the emergence of COVID-19, HRI was the appropriate center to coordinate, implement, and support the various clinical trials needed to study this lethal virus. Under the executive leadership of

www.hcahealthcarejournal.com

© 2020 HCA Physician Services, Inc. d/b/a Emerald Medical Education
Dr. Jon Perlin, HCA Healthcare’s chief medical officer and president of COG, and co-chaired by Dr. Ken Sands, an epidemiologist and HCA Healthcare’s chief safety officer, along with myself, a COVID-19 research steering committee and task force was put in place, with members representing various service lines, facilities and clinical specialties.

HRI’s efforts were quickly directed toward epidemiologic and registry research to better understand the disease and its impact on our diverse patient populations. Genospace, the bioinformatics and computational biology division of Sarah Cannon, based in Boston, was instrumental in this effort as data on over 100,000 COVID positive patients were captured across the system, including more than 60,000 who were hospitalized. Insights into age, race and ethnicity, along with comorbid conditions such as diabetes, obesity and lung disease were able to be quickly analyzed and explored. The impact and risks of drugs such as hydroxychloroquine, famotidine and dexamethasone were assessed in this vast database. Numerous manuscripts have been prepared and submitted, describing our findings for the broader public and scientific community.

Participation in therapeutic, preventive and testing strategies were also able to be implemented across the HCA Healthcare network. With the support of HRI and Sarah Cannon, our colleagues opened the convalescent plasma study at 175 HCA Healthcare facilities within just a few weeks, enrolling over 10,000 patients and helping the world understand when and how this therapy should be utilized. Other treatment modalities studied include antivirals, anti-inflammatories and antibodies, plus strategies such as extracorporeal membrane oxygenation (ECMO) and prone ventilation. We have also participated in numerous testing modalities, including rapid antigen, classic PCR and antibody tests, for both our patients and our health care workers and colleagues.

On the prevention front, similar strategies have been deployed to participate in the clinical trials of vaccine approaches, partnering with pharma, biotechs, and CROs to provide access to our HCA Healthcare communities. As I write this column, preliminary, but promising results from two of the vaccine trials have been released. Of note, both biotechs, Moderna and BioNTech (with Pfizer), had worked with Sarah Cannon on clinical trials of their personalized cancer vaccines, utilizing the same technology being deployed to prevent COVID-19. In fact, a Sarah Cannon patient was featured in a news release two years ago when she took the first ever cancer vaccine designed to fight her specific, individual cancer, and for which she is doing well. Vaccines are the great hope for our society getting past this pandemic, and we are still actively opening new vaccine studies at various locations in our markets.

Within HCA Healthcare, Sarah Cannon and HRI, we can be proud that during this pandemic, research not only did not slow down or stop, but it in fact expanded and accelerated. The contributions made and the ongoing observations will help greatly in the fight against COVID-19 and in our continued battle against cancer.

Conflicts of Interest

Dr. Burris reports grants from AstraZeneca, Incyte, Roche/Genentech, Bristol-Myers Squibb, MedImmune, Macrogenics, Novartis, Boehringer Ingelheim, Lilly, Seattle Genetics, Merck, Agios, Jounce Therapeutics, Moderna Therapeutics, CytomX Therapeutics, GlaxoSmithKline, Verastem, Tesaro, BioMed Valley Discoveries, TG Therapeutics, Vertex, eFFECTOR Therapeutics, Janssen, Gilead Sciences, BioAtla, CicaloMed, Harpoon Therapeutics, Arch, Arvinas, Revolution Medicine, Array BioPharma, Bayer, BIND Therapeutics, Kyocera, miRNA Therapeutics, Pfizer, Takeda/Millennium, Foundation Medicine and other funding from AstraZeneca, FORMA Therapeutics, Celgene, Incyte, Novartis, Pfizer, Daiichi Sankyo, HCA Healthcare/Sarah Cannon outside of the submitted work.

Dr. Burris is an employee of Sarah Cannon, an organization affiliated with the journal’s publisher.

This research was supported (in whole or in part) by HCA Healthcare and/or an HCA Healthcare affiliated entity. The views expressed in this publication represent those of the author(s) and do not necessarily represent the official views of HCA Healthcare or any of its affiliated entities.
Author Affiliation
1. Sarah Cannon Research Institute, Nashville, TN

References