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Foreword to the JCTS COVID-19 special issue

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Editorial

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The COVID-19 pandemic has been the medical challenge of our lifetimes. From being unknown in 2019, COVID-19 has been diagnosed in over 29 million people in the USA in 2020 and caused over 525,000 deaths through early 2021. It overwhelmed our healthcare systems, shut down most medical research and much of the economy, and caused unprecedented disruption to personal, family, and business relationships across the country, ushered in by "social distancing," a term new to our common vernacular.

COVID-19 was a particular challenge to our nation's biomedical research enterprise. A challenge not only to our ability to carry on vital research despite lab closures, but also to our capacity to respond to the urgent research needs of COVID-19 itself – its diagnosis, characterization, treatment, prevention, and sequelae, while at the same time supporting the increase clinical needs as well as enhanced public health response.

The National Center for Advancing Translational Sciences (NCATS) rapidly pivoted virtually all its programs to respond to COVID-19 in March 2020. NCATS' Clinical and Translational Science Awards (CTSA) program led NCATS' clinical response in ways that were uniquely impactful at a local, regional, and national level. Leaders of the CTSA hubs across the country managed and directed critical COVID-19 response efforts at their institutions and quickly shared their experiences, observations, and best practices on medical and operational adaptations to the pandemic through a network-wide communication mechanism established by the CTSA Center for Leading Innovation and Collaboration (CLIC). Clinical trials were initiated rapidly, many of which were facilitated by accelerated IRB review that was made possible by SMART IRB and IREx. Pivotal national multisite trials of convalescent plasma and immune modulators were carried out by large subsets of CTSA hubs and affiliated institutions. And in perhaps, the most ambitious EHR project ever undertaken, COVID-19 patient data were rapidly collected, harmonized, organized, and made available in a secure environment in just a few months, involving over 1000 people from the NCATS' informative program, the Center for Data to Health (CD2H), virtually every CTSA hub, many Institutional Development Award Network for Clinical and Translational Research institutions/organizations (IDeA-CTRs), and NCATS. This N3C enclave now contains detailed data on over 3 million people, which is being actively used in over 100 projects involving 1900 investigators from 500 institutions across the country to understand the pathogenesis, demographics, treatment of COVID-19, and its sequelae.

As the NIH leaders of the CTSA program, we were filled with pride, gratitude, and awe by the selfless, collaborative, and effective response from our community and stakeholders. We have together played a pivotal role in mitigating the worst effects of the pandemic on our patients, staff, trainees, and institutions. And, we have learned a great deal about how to enhance the translational process, how to utilize telemedicine and other remote technologies for care and research, and how to adapt to adversity. And, we have learned a lot about ourselves, our colleagues, and our individual and collective capacity for advancing translational science.

It is this last point that led to the creation of this remarkable JCTS Special Edition. Barry Coller and one of us (C.A.), as co-chairs of the CTSA Program Steering Committee, wanted to capture the learnings from COVID-19 while they were still fresh. We know that this will not be the last health crisis we face, and we wanted to memorialize what we did, what worked and what did not, what should be continued as common practice, and what should be avoided going forward. The ingenuity and ideas put forth will become a time capsule for the future. Barry led the charge to create this compendium, and scientists and staff from across the Steering Committee and the entire Consortium responded with enthusiasm to the opportunity. We thank the 100+ writers, the countless number of investigators and administrators who have provided information to inform these articles, the CTSA Program Steering Committee, and CLIC for their leadership in producing this edition in far less than a year.

In reading these articles and reliving the last year through them, we are again filled with pride and gratitude for all that was accomplished for our patients, our communities, and our nation. If anyone needed further proof that the CTSA program is the effective, collaborative, and transformative national network for translational science and medicine that it aspires to be, they need look no farther than this issue. We hope you enjoy and benefit from

its insights and keep them on your virtual bookshelf for regular reminders of what we did, and what we can do to bring the promise of science to patients in need.

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