



Cystic Fibrosis Research News

Title:

The Impact of SARS-CoV-2 on the Cystic Fibrosis Foundation Therapeutics Development Network

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What was your research question?

We wanted to understand the impact of Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) on cystic fibrosis (CF) clinical research within the Cystic Fibrosis Foundation Therapeutics Development Network (CFF TDN).

Why is this important?

It is important to monitor and understand the impact of SARS-CoV-2 on the TDN given there are many ongoing clinical trials currently being conducted across multiple sites within the TDN as well as being prepared for future trials. Understanding this impact allows the TDN Coordinating Center (TDNCC) to better support sites and sponsors as well as forecast and plan for future trials and assess the clinical research capabilities of individual sites.

What did you do?

We launched six surveys between April 2020 and July 2020. Each survey, sent using the Research Electronic Data Capture (REDCap) platform, was sent every two weeks to the

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Primary Research Coordinator contact at all TDN sites to understand the local impact on research team stability, capture ongoing and anticipated clinical research, and record the specific clinical and research procedures taking place at the sites. Sites were asked to respond within 3 days and a reminder was sent the morning of the deadline.

What did you find?

We found that SARS-CoV-2 had an early impact on participant enrollment, research team stability, and procedures such as spirometry and sputum induction. This impact steadily reduced over the months we surveyed as COVID-19 polices were implemented and research activities began to recover across the TDN.

What does this mean and reasons for caution?

The survey results proved essential in the TDNCC's ability to support sites over the first months of the SARS-CoV-2 pandemic. While SARS-CoV-2 created a significant barrier to clinical trial activity in the TDN, it also fostered resilience and innovation. Trial sites and sponsors rose to the challenge to keep research going in new and creative ways and to ensure that participants in clinical trials remained safe. A limitation is that each site had an individual response: some were unimpacted and able to maintain normal research activities while others are still significantly impacted and unable to conduct any clinical research.

What's next?

To continue monitoring the impact of SARS-CoV-2 on the TDN, a streamlined Smartsheet form was implemented in August 2020 to continue to collect a limited number of key data, which will allow the TDNCC to monitor the limitations to conducting research over the coming months.

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