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The Impact of COVID-19 on Clinical Trial Execution at the Dana-Farber Cancer Institute

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Abstract

Interventions designed to limit the spread of coronavirus disease 2019 (COVID-19) are having profound effects on the delivery of health care, but data showing the impact on oncology clinical trial enrollment, treatment, and monitoring are limited. We prospectively tracked relevant data from oncology clinical trials at Dana-Farber Cancer Institute from January 1, 2018, to June 30, 2020, including the number of open trials, new patient enrollments, in-person and virtual patient visits, dispensed investigational infusions, dispensed or shipped oral investigational agents, research biopsies, and blood samples. We ascertained why patients came off trials and determined on-site clinical research staffing levels. We used 2-sided Wilcoxon rank sum tests to assess the statistical significance of the reported changes. Nearly all patients on interventional treatment trials were maintained, and new enrollments continued at just under one-half the prepandemic rate. The median number of investigational prescriptions shipped to patients increased from 0 to 74 (range = 22-107) per week from March to June 2020. The median number of telemedicine appointments increased from 0 to 107 (range = 33-267) per week from March to June 2020. Research biopsies and blood collections decreased dramatically after Dana-Farber Cancer Institute implemented COVID-19related policies in March 2020. The number of research nurses and clinical research coordinators on site also decreased after March 2020. Substantial changes were required to safely continue clinical research during the pandemic, yet we observed no increases in serious adverse events or major violations related to drug dosing. Lessons learned from adapting research practices during COVID-19 can inform industry sponsors and governmental agencies to consider altering practices to increase operational efficiency and convenience for patients.

A previously unknown respiratory illness emerged in Wuhan, China, in December 2019. The causative agent was identified as the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and the associated disease was named coronavirus disease 2019 (COVID-19) (1–3). The first verified COVID-19 patient in the United States became ill in January 2020 in Washington State (4). The virus has now spread rapidly throughout the United States and caused more than 5.6 million cases and nearly 176 000 deaths by late August of 2020 (5).

The spread of this deadly virus has led to substantial changes in public policies throughout the United States that have impacted travel, public gatherings, and access to medical care in the inpatient and outpatient settings, including elective procedures and nonemergent clinical services (6). Oncology care is commonly critical, and most of the care is administered in the outpatient setting. This has led members of the oncology community to provide guidance for managing the treatment of cancer patients during this pandemic (7,8). Clinical trials are essential for advancing cancer treatment and also provide access to novel and potentially effective treatments for patients. The public policies enacted around the United States to reduce the spread of COVID-19 have prompted the National Cancer COMMENTARY

Institute (9) and the Food and Drug Administration (10) to issue guidelines around the conduct of clinical trials.

Dana-Farber Cancer Institute (DFCI) and Brigham Health (BH) are located in Massachusetts, which had the 12th highest number of COVID-19 cases and the 4th highest number of deaths in the United States by early August 2020 (5). As the threat emerged, the Commonwealth of Massachusetts enacted a series of public health policies to protect its citizens and visitors. Governor Charles Baker issued a state of emergency to respond to COVID-19 on March 10, 2020, when there were 91 known cases of COVID-19 in the state (11). DFCI and BH followed the policies set forth by the Commonwealth of Massachusetts, including a stay-at-home advisory on March 23, restrictions on gatherings of 10 or more people, and other policies that are affecting the methods and the ability to deliver health care to our patients. In addition, DFCI and BH had to ensure that there were adequate resources to care for the anticipated surge in COVID-19 admitted inpatients in April of 2020 (12,13). On May 18, 2020, Governor Baker instituted phase I of the stepwise reopening of businesses and other organizations in Massachusetts. Phase II, step 1 was subsequently initiated on June 1, 2020, followed by phase II, step 2 on June 19. In response, DFCI and BH instituted a phased recovery plan beginning on May 18, 2020 (11-13).

Although the cancer community has provided guidance for managing patients with cancer and federal agencies have issued guidelines for clinical trials, there are little objective data to assess the impact of public and institutional policies for patients who are considering or already enrolled in clinical trials. The Office of Clinical Research at DFCI monitors clinical trials by assembling pertinent data and providing feedback to study teams. In the months following the enactment of the public policies meant to limit the spread of COVID-19, as well as policies to ensure access to acute medical care for patients who contracted the virus, we assessed the ability to carry out interventional treatment clinical trials in this challenging environment.

Methods

Metrics and Data Collection

The Office of Clinical Research has prospectively tracked metrics for clinical trials from 2015 to the present. We retrieved the dates and specifics of the COVID-19–related institutional policies that affected clinical care and clinical trials at DFCI from online staff communications. The objective information deemed pertinent to the changes in clinical trial execution was identified by the chief clinical research officer, deputy chief clinical research officer, the chair of the Executive Committee on Clinical Research, the associate chief nurse for clinical research, the director of research nursing, and the administrative director for the Office of Clinical Research. The list was distributed to the study teams, who gathered the relevant information.

The number of patients accrued to clinical trials by month was retrieved from January 1, 2018, through June 30, 2020, from the OnCore Clinical Trial Management System Enterprise Research system. The information on other parameters was gathered by the study teams from January 1, 2020, to June 30, 2020, with a few exceptions as noted below. The number of studies that were open but were not able to enroll and the number of patients and reasons for coming off the clinical trials were ascertained. The number of research biopsies performed each month (from January 1, 2018, to June 30, 2020) was prospectively monitored and enumerated. The number of research blood samples collected was retrieved by monitoring the kits used for drawing the research blood. The number of inperson patient visits and virtual visits by week was retrieved from the electronic medical records. The number of investigational infusions (from January 1, 2018, to June 30, 2020), oral agents dispensed in the outpatient pharmacy, and oral agents shipped to patients were prospectively monitored and retrieved from the electronic investigational drug accountability system (nCoup, Fremont, CA). Research management provided research nursing and clinical research coordinator (CRC) staffing levels from March 16, 2020, to June 30, 2020, the number of trials that held accrual due to COVID-19, and the number of patients who came off trials due to COVID-19.

Statistical Analysis

The statistics team used various statistical methods and models to assess the clinical research changes over time. The Wilcoxon rank sum test (2-sided) was used to evaluate the time effect on the following factors: the number of patients enrolled to interventional treatment studies; the number of patients enrolled to interventional, nontreatment studies; the number of patients enrolled to noninterventional studies; the number of interventional treatment trials; the number of infusions of investigational agents; the number of biopsies for research purposes; and the number of research blood collections associated with therapeutic trials. The time factor was trinary, with 2018, 2019, and January-February 2020 collapsed into 1 group; March-May 2020 coded as another group; and June coded as the third group as DFCI and BH instituted a phased recovery plan coordinated with the State of Massachusetts policies. Linear spline regression models were fit to assess the following associations: the proportion of investigational agents dispensed weekly by mail from January to June 2020; the proportion of patients (adult or pediatric) evaluated by telemedicine appointments over the weeks from March 16 to June 28, 2020; the number of missed appointments either in-person or via telemedicine over the weeks from March 16 to June 28, 2020; the proportion of research nurses working remotely over the weeks from March 16 to June 28, 2020; and the number of CRCs working on-site over the weeks from March 16 to June 28, 2020. The week of May 31, 2020, was picked as the spline knot for all the linear spline models. We wanted to examine whether the recovery policy issued on May 28, 2020, at DFCI had any effect on the clinical practices previously described. The statistics team performed all analyses using SAS 9.4. P values less than .05 were considered statistically significant.

Results

The ongoing guidance from the Commonwealth of Massachusetts, the National Cancer Institute, and the Food and Drug Administration prompted DFCI to enact progressively restrictive guidelines for clinical research operations from March through April 2020 (Box 1). Operational restrictions at BH made in preparation for the COVID-19 patient surge further affected clinical research at DFCI. Specifically, the procurement of image-guided percutaneous biopsies for research purposes was temporarily limited to only support research that had the potential to be lifesaving or disease altering in circumstances where no alternative clinical treatments were available. These policies necessitated adjustments to our staffing models and

	cies for carrying out clinical research at Dana-Farber Cancer Institute (DFCI) from March 13 through June 13	-,
T1	Restrictions	
Level	Description	Effective date
Level 1	Minimal restriction – Clinical research work may continue as usual, but staff should reduce their time on-site and work from home when possible.	March 13, 2020
Level 2	Staffing restriction – Only staff who are necessary to continue clinical research activities should be on- site.	N/A ^a
Level 3	 Reduced staffing to carry out clinical research – Those needed for direct interaction with patients to carry out clinical research needs. Staff should consolidate their roles to: Clinicians needed to see protocol patients 	March 16, 2020
	 Research nurses and CRCs who typically secure consents and assess patients on studies Research pharmacy staff 	
	Cell manipulation core facility staff	
	 Laboratory staff that process research samples from patients enrolled in active clinical trials Research staff in Office for Human Research Subjects, Research Informatics Operations, Office of 	
Level 4	Data Quality, and Clinical Trials Office will largely be working off-site At Dana-Farber:	March 20, 2020
	 Nontherapeutic research not directly related to patient care will be suspended. 	
	Research staff will focus on maintaining active research protocols and patients on these studies.	
	 Continue consenting patients to existing therapeutic protocols as resources allow. 	
	• Only those needed for direct interaction with patients to address clinical research needs can be on site:	
	Clinicians needed to see the protocol patientsThe number of research nurses and CRCs will be consolidated to minimize patient contact.	
	Research pharmacy staffCell manipulation core facility staff	
	 Laboratory staff who process research samples from patients enrolled on active clinical trials Recovery 	
Stage	Description	Effective date
Stage 1	At Dana-Farber	May 18, 2020
	 Preparations underway to progress to stage 2A 	· , · , · - ·
Stage 2A	At Dana-Farber	May 28, 2020
	• PFTs available: resting oximetry, 6-minute walks, exercise oximetry	<i>.</i>
	CRL began accepting all clinical trial-related samples	
	No restrictions to collecting biospecimens for therapeutic clinical trials	
	• CSIR research biopsies for therapeutic trials may be scheduled as capacity allows (regardless of	
	whether a sample is sent to BWH Pathology)	
	Triplicate ECGs allowed when required by protocol	
	Minimum number of CRCs needed to collect biospecimens permitted on-site	
Stage 2B	At Dana-Farber	June 11, 2020
	Study patients should be scheduled for on-campus visits whenever possible	
	Tissue banking from BWH surgical procedures (non-CSIR) resumed (June 22, 2020)	
	• Up to 5 CRCs allowed on-site per disease center per day	
	 1 RRN for every 10 patients allowed on-site per day 	

^aGiven the rapid changes in local and national guidance, DFCI escalated from level 1 to 3, without an intermediate level 2 reduction in staffing and services. BWH = Brigham and Women's Hospital; CRC = clinical research coordinator; CRL = clinical research laboratory; CSIR = cross-sectional interventional radiology; ECG = electrocardiogram; N/A = not applicable; PFT = pulmonary function test; RRN = research registered nurse.

delivery of care to patients enrolled and screened for clinical trials. The Office of Clinical Research worked with DFCI to provide guidance to study teams, and we assessed the impact on patients and compliance by our staff.

As of March 20, 2020, DFCI was at level 4 research (Box 1). In addition to other changes, level 4 restrictions limited the number of research nurses and study coordinators who could be on-site, all monitoring of trials was required to be conducted remotely, and biospecimen collection was restricted due to the reduction in on-site staff available to collect and process samples. On May 18, 2020, DFCI initiated stage 1 of recovery, which involved preparing to resume seeing patients in person and collecting biospecimens for therapeutic and nontherapeutic trials. Collection of biospecimens for therapeutic clinical trials resumed when stage 2A of recovery was implemented on May 28, 2020, in which the minimum number of CRCs needed to collect samples was permitted on site. Stage 2B was initiated on June 11, which allowed for study patients to be seen in person whenever possible, with up to 5 CRCs per disease center and 1 research nurse for every 10 trial patients allowed on site per day (Box 1).

Trials with eligibility criteria and study requirements for onstudy biopsies, frequent clinic visits, extended pharmacokinetic assessments, and other research blood collections were particularly affected by level 4 restrictions. In addition, sponsors' decisions to pause enrollment also had an impact. For each clinical trial, the principal investigator was asked to ensure the resources needed to enroll and safely maintain the participants on the study were available, and the sponsor agreed to adapt the





Figure 1. Number of patients enrolled in trials by month, January 2019 to June 2020. A) Number of patients who enrolled in interventional, therapeutic trials by month, January 2019 to June 2020. B) Number of patients who enrolled in interventional, nontherapeutic trials by month, January 2019 to June 2020. C) Number of patients who enrolled in noninterventional, nontherapeutic trials by month, January 2019 to June 2020. C) Number of patients who enrolled in noninterventional, nontherapeutic trials by month, January 2019 to June 2020. C) Number of patients who enrolled in noninterventional, nontherapeutic trials by month, January 2019 to June 2020. Two-sided Wilcoxon rank sum tests were used to compare the number of patients enrolled across the 3 time periods: 2018-February 2020, March-May 2020, and June 2020.

Table 1. Impact of COVID-19-related policies on trial accrual, number of open trials, infusions of investigational agents, and collection of research biospecimens per month at Dana-Farber Cancer Institute

	Median (range)			
Affected metric	Jan 2018-Feb 2020	Mar 2020-May 2020	June 2020	Pª
Patients enrolled in treatment trials, No.				
Interventional, treatment	205 (157-241)	86 (83-140)	138	.007
Interventional, nontreatment	161 (85-311)	103 (65-119)	202	.08
Noninterventional	1870 (1374-2531)	255 (128-1369)	380	.007
Interventional treatment trials, No.	539 (523-591)	552 (548-568)	549	.31
Infusions of investigational agents	1462 (984-1837)	802 (774-996)	842	.008
Biopsies for research purposes	85 (67-110)	1 (0-52)	17	.006
Blood collection for research purposes	1142 (545-1328)	243 (199-812)	776	.02

^aThese P values still show a decreasing trend across time in general. None of the increases from March-May to June was statistically significant.

protocol requirements to existing conditions brought on by the pandemic.

A median of 205 patients per month (range = 157-241) enrolled in medical oncology interventional treatment studies from January 2018 to February 2020. The number fell dramatically between March and May 2020 to a median of 86 patients (range = 83-140) before beginning to recover in June 2020, with 138 accrued (Figure 1, A). In general, the trend was decreasing (P = .007). The recovery from March through May to June was not statistically significant (P = .65). Although new enrollments declined, only 7 of the 2295 (0.3%) active patients already on interventional treatment trials came off study, due to either concerns about contracting COVID-19 or international travel restrictions. Similar decreasing trends were observed for patients enrolled in interventional, nontreatment studies (Figure 1, B; P = .08) and noninterventional, nontreatment studies (Figure 1, C; P = .007) (Table 1).

As shown in Table 1, the median number of interventional treatment trials accruing patients at DFCI by month remained

largely stable between February and June 2020. Nevertheless, since the COVID-19-related policies were instituted, 49 of the 568 enrolling trials (8.6%) were closed (temporarily or permanently) and 154 (27.1%) were put on hold (many of which were put on hold due to restrictions on biospecimen collection). Additionally, 41 institutional review board-approved trials were not activated as of the end of June 2020 due to COVID-19 restrictions. The enactment of COVID-19-related policies also resulted in a statistically significant reduction in the monthly infusion of investigational agents, collection of biopsies for research purposes, and blood collection for research purposes (Table 1).

The research pharmacy at DFCI dispensed a median of 272 outpatient oral investigational prescriptions per week (range = 225-324) from January 5, 2020, through March 22, 2020 (Figure 2, A). The guidance from the National Cancer Institute and the Food and Drug Administration called for increased flexibility in shipping investigational agents directly to patients. In response, in March 2020, the research pharmacy, with the assistance of



Figure 2. Changes in oral investigational agent distribution, appointment setting, and missed appointments from January 2020 to June 2020. A) Number of oral investigational agents dispensed in person vs shipped to patients by week, January 2020 to June 2020. B) Number of adult appointments conducted in-person and using telemedicine, January 2020 to June 2020. C) Number of pediatric appointments conducted in-person and using telemedicine, January 2020 to June 2020. D) Number of adult missed appointments, in-person and via telemedicine, January 2020 to June 2020.

research nursing and CRCs, began a program to mail investigational prescriptions to participants rather than requiring inperson pick-up at the DFCI outpatient pharmacy. Ten sponsors provided blanket approval to ship investigational oral agents, and 2 sponsors did not provide this approval.

The total oral investigational agents dispensed ranged from 232 to 276 (median = 251) per week during the 14-week period between March 26 to the week of May 31, 2020. The number of mailed investigational agents ranged from 49 to 107 per week (median = 85) from March 29 to the week of May 31, 2020. In total, the median number of investigational prescriptions shipped to patients increased from 0 to 74 (range = 22-107) per week from March 2020 to June 2020, and mailed investigational agents represented 32.0% of all dispensed investigational agents during this time. The number of mailed investigational agents decreased to a median of 31 per week (range = 22-37) and represented 11.8% of all dispensed investigational agents from the week of June 7 to June 28, 2020 (Figure 2, A). We observed a statistically significant decrease in the percentage of mailed investigational agents from March 26 to the week of May 31, 2020 (P = .003); the decreasing trend did not statistically significantly alter after June (P = .22).

As part of the COVID-19 policies, providers at DFCI began seeing many new and established patients through telemedicine appointments during the week of March 16, 2020. The median number of telemedicine appointments increased from 0 to 107 (range = 33-267) per week from March 2020 to June 2020. The number of adult telemedicine research-related appointments peaked at 267 during the week of April 12 (Figure 2, B). The percentage of telemedicine appointments for adults from March to the end of May was stable (P = .30), but we report a statistically significant decrease beginning in the month of June (P = .02). The number of pediatric telemedicine research-related appointments peaked at 11 during the weeks of April 12 and May 3 (Figure 2, C). There was no statistically significant change in the percentage of telemedicine appointments for pediatric patients either from March to May or in June (P = .95, P = .75, respectively).

We also tracked missed appointments for patients on clinical trials each week from January to June 2020. Missed appointments spiked during the week of March 15, 2020 (Figure 2, D), as DFCI was rapidly transitioning from level 1 to level 4 research restrictions (Box 1). As providers began seeing patients through telemedicine appointments, a roughly equal proportion of patients missed in-person and telemedicine appointments from late April to early June 2020. Starting from the week of March 15, the number of missed in-person appointments decreased to the end of May (P = .04) but became stable during the recovery (P = .44). We observed a statistically significant increase in the number of missed telemedicine appointments from the week of March 15 to the end of May (P = .003) and then a statistically significant decrease during the recovery (P < .001) (Figure 2, D).

DFCI has 95 research nurses in both medical and pediatric oncology. Before March 16, 2020, no research nurses worked remotely. After the implementation of COVID-19 policies, the number of research nurses working on-site in the clinic ranged from 17 to 36 per week (median = 20) between the weeks of March 16 and May 31, 2020. The number of research nurses working remotely ranged from 43 to 65 per week (median = 59) during this time. In June, the number of research nurses working on-site in the clinic ranged from 24 to 31 per week; the number of research nurses working remotely ranged from 51 to 58 per week during this time. There was a statistically significant increase in the percentage of nurses working remotely from March to the week of May 31, 2020 (P < .001), then a statistically significant decrease during the recovery (P < .001).

In January 2020, 165 CRCs worked on-site at DFCI. Between March 16 and May 31, the number of CRCs on-site per day varied between 20 and 41, with a median of 28 on-site each day. Between June 1 and June 30, the number of CRCs on-site per day varied between 39 and 59, with a median of 51 on-site each day. The number of CRCs on-site per day was stable from March to the end of May (P = .57), but there was a statistically significant increase during the recovery (P < .001). Most disease centers maintained a rotating schedule for CRCs.

To assess the impact of COVID-19-related policies on patient compliance to protocol therapy, we recorded the number of protocol violations related and not related to dosing of protocol therapy by month. In January and February of 2020, there was a median of 15 dosing-related protocol violations among a median of 2424 patients on treatment (3.34-8.98 \times 10⁻³ violations per patient on treatment) and 54 nondosing-related protocol violations (2.13-2.29 \times 10⁻² violations per patient on treatment). From March to May 2020, there was a median of 10 dosingrelated protocol violations among a median of 2347 patients on treatment (range = $3.42-5.53 \times 10^{-3}$ violations per patient on treatment) and 24 nondosing-related protocol violations (range = 9.80 \times 10⁻³ to 1.63 \times 10⁻² violations per patient on treatment). In June 2020, there was 1 dosing-related protocol violation and 15 nondosing-related protocol violations among 2391 patients on treatment.

In addition, we assessed the number of clinically significant adverse events (SAEs) per patient on treatment before and after the institution of COVID-19–related policies. In January and February of 2020, there was a median of 51 SAEs among a median of 2424 patients on treatment (range = $1.76-2.42 \times 10^{-2}$ SAEs per patient on treatment). From March to May of 2020, there was a median of 30 SAEs among a median of 2347 patients on treatment (range = $1.07-1.92 \times 10^{-2}$ SAEs per patient on treatment). This number decreased to 21 SAEs among 2391 patients on treatment in June 2020.

Finally, we reviewed patient complaints and did not observe any complaints specific to the execution of clinical trials under the COVID-19–related restrictions.

Discussion

The ongoing COVID-19 pandemic is placing tremendous strain on the health-care system. Medical and pediatric oncology programs have been particularly affected due to the ongoing need to provide optimal care to cancer patients while limiting their potential for contracting COVID-19 (14,15). In addition to routine care, therapeutic clinical trials have also been affected by policies designed to protect patients and staff from COVID-19. Despite the limitations imposed by social distancing requirements, travel restrictions, remote work policies, and limited support staff for correlative studies, DFCI was able to continue enrolling patients in therapeutic clinical trials at approximately one-half the pre-COVID-19 rate; moreover, nearly all the patients previously enrolled were able to stay on the studies. This continued new enrollment and treatment for existing participants was mostly due to practice modifications that allowed patients to participate remotely as recommended by our state and federal agencies. These include performing adverse event assessments via telehealth visits and mailing investigational agents to patients' homes. Also, more than one-half of the research nurses and the majority of CRCs began working remotely once the COVID-19 policies were implemented. This allowed DFCI to maintain a full research staff, albeit under modified working conditions. As businesses and other organizations in Massachusetts began to reopen in late May and throughout June, DFCI began a staged recovery process to resume

scheduling of study patients for on-campus visits and collection of biospecimens for therapeutic and nontherapeutic trials.

It is important to point out several limitations of this prospective study. Before the institution of the COVID-19–related policies, the research pharmacy did not ship oral medications directly to patients unless it was an emergency situation and approved by the sponsor and principal investigator. However, the precise number of shipped medications was not centrally tracked; this means that the baseline number of investigational agents shipped to patients before the week of March 29, 2020, is not clearly known but was very rare. Second, the number of CRCs and research nurses on-site was obtained by surveying clinical research managers in each disease center and nursing leadership in medical and pediatric oncology. However, it is possible that not all schedule changes were captured by the managers' records.

It is important to consider that the experience at DFCI might not reflect the situation at all cancer centers around the country, because policies and resources differ by center. A recent American Society of Clinical Oncology survey of 32 cancer centers (14 academic centers and 18 community programs) revealed that 64% of the centers had developed formal policies related to the delivery of cancer care and conduct of clinical trials during the COVID-19 pandemic. The policies at many of the sites included provisions such as telehealth visits for patients (87.5%), remote work by research staff (75%), and remote monitoring by sponsors and/or contract research organizations (71.9%), which are also part of the COVID-19 policies at DFCI and BH. Even with these modifications, 59.4% of the surveyed centers had halted screening and/or enrollment for clinical trials and had ceased research-only visits, except for those providing cancer treatments. In addition, roughly one-half of the responding centers had ceased research-only blood draws and/or tissue collections, similar to our institutions (16).

The continued enrollment in therapeutic clinical trials at DFCI and other cancer centers around the country during COVID-19 demonstrates that cancer clinical research is robust and can be adapted to changing circumstances. Additionally, these changes can be adopted without compromising safety, as seen by a lack of increase in serious adverse events and major violations. However, it is prudent to consider the changes taking place not only as stopgap measures to respond to a temporary health crisis, but perhaps also as considerations in long-term improvements in clinical trial design to reduce the burden on study participants and research staff (17). Many of the modifications made to ensure the safety of patients and staff during COVID-19, including telehealth visits, remote monitoring, and shipping of investigational agents, could benefit cancer patients in general as the pandemic wanes. Frequent traveling to the clinic in particular has been identified as a source of difficulty for cancer patients and a barrier to participation in clinical trials (18,19), particularly for ethnic and racial minorities (20,21). Reducing the number of required visits for clinical trials would eliminate unnecessary stress and allow cancer patients to spend more time with their families, potentially increase the ethnic diversity of clinical trial participants, and improve overall quality of life.

COVID-19 is likely to be relevant throughout 2020 and into 2021. Even as the threat eases, we should use this situation as an opportunity to reevaluate standard practices for clinical trials. Making clinical trials more accessible, and less stressful for potential patients, would allow for broader participation. This would have immediate and future benefits for cancer patients and could streamline the development of effective cancer therapies.

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Data Availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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