

Patterns of Enrollment in Cancer Treatment Trials During the COVID-19 Pandemic at National Cancer Institute–Designated Cancer Centers

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Abstract: The COVID-19 pandemic posed unprecedented strain on enrollment to cancer clinical trials and their conduct. Here, we highlight an analysis using information from the National Cancer Institute (NCI) Clinical Trials Reporting Program database to describe enrollment patterns to interventional cancer treatment trials at NCI-Designated Cancer Centers during the pandemic. Enrollment to cancer treatment trials at NCI-Designated Cancer Centers decreased precipitously early in the pandemic and has not yet fully returned to the 2019 baseline as of mid-2021. We discuss possible reasons for this and how some of the changes in clinical trial conduct implemented during the pandemic may become part of the standard conduct of NCI-supported clinical trials and broaden access to trials.

Key Words: Cancer clinical trials, Clinical Trials Reporting Program, COVID-19 pandemic, NCI-Designated Cancer Centers

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The coronavirus disease 2019 (COVID-19) pandemic markedly disrupted the conduct of cancer clinical trials beginning in early 2020. The National Cancer Institute (NCI) and the US Food and Drug Administration (FDA) rapidly developed guidance for the operation of cancer clinical trials to minimize the impact of the pandemic for patients currently enrolled or in need of a clinical trial.^{1,2} Not unexpectedly, enrollment of new patients to cancer clinical trials declined sharply beginning in March 2020. Several reports have described the deleterious effect of the pandemic on cancer clinical trial participation at individual academic institutions or NCI National Clinical Trials Network (NCTN) groups. However, none have addressed the impact of the pandemic on enrollment to cancer treatment trials throughout NCI-Designated Cancer Centers (DCCs), a major component of the nation's cancer research infrastructure.^{3–6} There are currently 64 NCI-DCCs (51 comprehensive cancer centers and 13 clinical cancer centers)

located in 35 states and the District of Columbia that are funded to deliver cutting-edge treatments and clinical trials to patients as part of their mission.⁷ The purpose of this report is to describe the pattern of enrollment to cancer treatment trials at NCI-DCCs during the COVID-19 pandemic.

METHODS

NCI's Clinical Trials Reporting Program Database

NCI's Clinical Trials Reporting Program (CTRP) database contains registration information on all interventional clinical trials conducted at NCI-DCCs open to enrollment on or after January 1, 2009, regardless of trial sponsor. Registration elements encompass all the basic trial registration information required by the National Library of Medicine's ClinicalTrials.gov database,⁸ as well as additional elements, for example, study source, required for inclusion in a P30 NCI Cancer Center Support Grant.⁹ Study source categories include (1) national: NCI- or National Institutes of Health (NIH)-supported clinical trials conducted by NCI national networks such as the NCI NCTN; (2) externally peer-reviewed: clinical trials supported by NCI or NIH grants (other than NCI national networks) or other select sponsors that utilize peer review; (3) institutional: clinical trials for which the cancer center investigator has primary responsibility for conceptualizing, designing, and implementing the trial and reporting results; (4) industrial: clinical trials for which a pharmaceutical company controls the design, implementation, and results reporting. Table 1 provides full definitions of the study source and examples of this categorization utilized by the NCI Cancer Centers program.

National Cancer Institute DCCs have been required to register any interventional trial open to enrollment at their center since January 1, 2009, and report enrollment data quarterly for all trials other than NCI national trials since January 1, 2013. Clinical trials are classified at the time of registration into one of the following primary purpose categories as defined by ClinicalTrials.gov: treatment, screening, prevention, diagnostic, supportive care, health services research, basic science, device feasibility, and other. Patient-level enrollment data for NCI supported national trials including date of patient enrollment and demographic information are transferred internally from NCI's Division of Cancer Treatment and Diagnosis and Division of Cancer Prevention databases to CTRP. National Cancer Institute DCCs submit patient-level enrollment data for other nonindustrial trials. Summary enrollment data, a total count of enrollments, are reported by NCI-DCCs for industrial clinical trials.

Data and Analysis

We examined all interventional clinical trials with a primary purpose of treatment in the NCI CTRP database as of November 22, 2021. Treatment trials other than phase IV that were open to enrollment at 1 or more of the 64 NCI-DCCs conducting clinical trials at any point in time between January 1, 2019, and June 30,

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TABLE 1. Study Source Categories for Interventional Clinical Trials as Defined by the NCI P30 Cancer Center Support Grant Data Table Guide v3.1.1*

Study Source Category	Definition	Examples
Nonindustrial		
National	Clinical trials supported by NCI or NIH national networks	<ul style="list-style-type: none"> • NCI National Clinical Trials Network trials • NCI Experimental Therapeutics Clinical Trials Network trials • NCI Community Clinical Trials Oncology Research Program trials • Pediatric Early Phase Clinical Trials Network
Externally peer-reviewed	Clinical trials supported by NCI or NIH grants other than NCI national networks; also includes trials supported by other sponsors that utilize peer review	<ul style="list-style-type: none"> • Non-NCI network trials supported by R01, P01, P50, R21, etc., grants • Trials supported by other funders that utilize peer review. Examples of those organizations can be found at: https://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf
Institutional	Clinical trials for which the cancer center investigator has primary responsibility for conceptualizing, designing, and implementing the trial and reporting results	<ul style="list-style-type: none"> • In-house clinical trials authored or coauthored by cancer center investigators that undergo scientific peer review solely by the Protocol Review and Monitoring System of the Cancer Center.
Industrial	Clinical trials for which a pharmaceutical company controls the design, implementation, and results reporting	<ul style="list-style-type: none"> • A clinical trial written by a pharmaceutical company that the cancer center is a participating site.

*<https://cancercenters.cancer.gov/GrantsFunding/DataGuide>.

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2021, were identified and included in the analytic data set. All 64 NCI-DCCs confirmed enrollment reporting was complete for 2019 and 2020. Enrollment data submissions through March 31, 2021, and June 30, 2021, were confirmed complete for 63 and 62 centers, respectively. The 2 centers with partial 2021 enrollment data indicated that the data submitted represented most of their enrollment.

To compare prepandemic and postpandemic enrollment, we defined 2019 as the prepandemic baseline enrollment period. Total annual enrollment was tabulated for each year (2019, 2020, and the first 6 months of 2021) for all trials, for each of the 4 study source categories (national, externally peer-reviewed, institutional, and industrial), and for each of the following trial phase groupings: phase I, phase II (includes phase I/II trials), phase III (includes phase II/III trials), and phase nonapplicable (N/A).

Monthly enrollment was assessed only for nonindustrial trials because date of patient enrollment were not available for industrial studies. Total monthly enrollment to all nonindustrial trials from January 1, 2019, through June 30, 2021, was tabulated for each of the study sources (national, externally peer-reviewed, and institutional) and each phase category excluding phase N/A.

To compare prepandemic and postpandemic enrollments, we then determined the proportion of 2019 monthly enrollment for each analogous month in 2020 and the first 6 months of 2021 overall and for each study source and phase category. For example, to determine the percent proportion that the total January 2020 enrollment was of the January 2019 total enrollment, we divided the total January 2020 enrollment by the total January 2019 enrollment and multiplied the proportion by 100. To determine the percent proportional change in enrollment for each month compared with 2019, we subtracted the monthly enrollment from the 2019 enrollment and divided the difference by the 2019 enrollment and multiplied the proportion by 100.

RESULTS

Overall Enrollment

A total of 7252 treatment clinical trials other than phase IV studies were open to enrollment at 1 or more NCI-DCCs at any

point in time during the analysis period, January 1, 2019, to June 30, 2021. There was not a substantial difference in the number of trials open to enrollment by year: 5438 trials in 2019, 5339 trials in 2020, and 5124 in the first half of 2021 through June 30, 2021. Trials excluded from further analysis were 263 nonindustrial trials with 5347 enrollments because of missing date of enrollment. The remaining 6989 trials open to accrual included 4063 nonindustrial trials (national, externally peer-reviewed, or institutional) and 2926 industrial trials. Of these, 5705 trials reported at least 1 enrollment between January 1, 2019, and June 30, 2021. These included 1840 (32.3%) phase I trials, 3134 (54.9%) phase II trials, 589 (10.3%) phase III trials, and 142 (2.5%) phase N/A trials.

Enrollment totaled 111,902 during the overall time period, with 58.8% (65,745) of the enrollment to nonindustrial clinical trials (14.8% [16,524] national, 6.4% [7116] externally peer-reviewed, and 37.6% [42,105] institutional; Table 2). The proportions of enrollment by study source for each of the full years 2019 and 2020 and the half-year for 2021 were similar to the overall enrollment pattern, with nearly 60% of patients enrolled to nonindustrial trials. Figure 1 demonstrates the nearly 15% overall decline in annual total enrollment for 2020 compared with 2019, as well as the decline in all study source categories (industrial 13.7%, externally peer-reviewed 30.5%, and institutional 18.1%), except for national trials. The half-year data for 2021 suggest that enrollment is on track for improvement over 2020, but will not fully recover to 2019 levels if the current trend continues.

Nonindustrial Trial Enrollment

The monthly enrollment and percent change in enrollment for 2020 and 2021 compared with the same month in 2019 for the nonindustrial clinical trials overall and for each study source category are presented in Table 3. The average overall monthly enrollment for nonindustrial trials was 2397 (range, 2102–2620) for 2019, 2034 (range, 1192–2501) for 2020, and 2097 (range, 1946–2312) (Table 3A). The percent change in the average monthly enrollment for 2020 compared with 2019 decreased by 15.1% and by 12.5% for 2021. The lowest monthly enrollment was 1192 in April 2020 immediately after the start of the pandemic, representing a 53.3% decrease from April 2019. Figure 2 displays the sharp

TABLE 2. Annual Enrollment and Number of Trials Open to Accrual With Enrollment, January 2019 to June 2021

Study Source	Trials Open to Accrual With Enrollment, No.* (%)				Enrollment, No. (%)			
	Total Study Period	2019	2020	2021† Jan 1–Jun 30	Total Study Period	2019	2020	2021† Jan 1–Jun 30
Nonindustrial								
National	391 (6.8)	273 (6.8)	278 (6.9)	255 (7.6)	16,524 (14.8)	6689 (13.8)	6747 (16.3)	3088 (13.9)
Externally peer-reviewed	340 (6.0)	278 (6.9)	241 (6.0)	182 (5.4)	7116 (6.4)	3378 (7.0)	2348 (5.7)	1390 (6.2)
Institutional	2657 (46.6)	1945 (48.6)	1934 (48.2)	1624 (48.1)	42,105 (37.6)	18,694 (38.7)	15,310 (37.1)	8101 (36.3)
Industrial	2317 (40.6)	1509 (37.7)	1559 (38.9)	1313 (38.9)	46,157 (41.2)	19,565 (40.5)	16,885 (40.9)	9707 (43.6)
Total	5705	4005	4012	3374	111,902	48,326	41,290	22,286

*Trials open to enrollment at 1 or more NCI-DCCs with at least 1 enrollment.

†Half-year enrollment only, January 1 to June 30, 2021.

drop in absolute number of enrollments beginning at the start of the pandemic in March 2020 and lasting until June 2020 when enrollments began to increase, but that they have not yet fully recovered as of June 2021.

Figure 3 compares the monthly enrollments to national, institutional, and externally peer-reviewed clinical trials for January 2020 to June 2021 as percent proportion of the 2019 comparable month and demonstrates that while enrollment to all categories of trials plunged around the start of the pandemic in March 2020, the fall was greatest for externally peer-reviewed trials, followed by institutional trials, and least for national trials. The pattern of recovery has been similar in that national trials have had the greatest recovery, followed by institutional trials, with externally peer-reviewed trials trailing behind. It is notable that of all the nonindustrial trials, enrollments to national trials have had the strongest recovery and that monthly enrollment in the last 4 months of 2020 exceeded monthly enrollments in the same months of 2019. This rebound has not been fully sustained as reflected by the small dip (~8%) in average monthly enrollment for the first 6 months of 2021 (Table 3B–D).

Total enrollment for all phases of nonindustrial clinical trials excluding phase N/A was 62,887 patients from January 1, 2019, to June 30, 2021 (10,107 phase I, 37,176 phase II, and 15,604 phase III). Figure 4 compares the monthly enrollments for phases I, II, and III trials as a percent proportion of the 2019 comparable month. The sharp decline in enrollment surrounding the start of

the pandemic affected phase III trials to a lesser extent than phases I and II trials, and over time phase III trials have had a stronger recovery than phases I and II trials.

DISCUSSION

Our analysis demonstrates that the profound decrease in enrollment to cancer treatment clinical trials at NCI-DCCs during the early months of the COVID-19 pandemic has not yet fully returned to prepandemic levels, although there has been a substantial recovery from the lowest point. While the pattern of the change in enrollment over time was similar across the types of treatment trials, the magnitude of the effect was not uniform across trial types. The sharp plunge in early 2020 was less for national trials, and the recovery was greater compared with externally peer-reviewed and institutional trials, where recovery continues to lag. Similarly, phase III trials were impacted less and have recovered more than phases I and II trials. Our findings are consistent with reports that some institutions initially prioritized national and later phase trials or those with potential for the greatest clinical benefit while minimizing correlative procedures.^{3,6}

Although there may be several reasons why enrollments have not fully recovered to prepandemic levels, staff turnover or a decrease in clinical trial staff due to reassignment of clinical trials research staff to other health care activities may be a contributing factor. Anecdotal reports from some NCI-DCCs and a recent blog

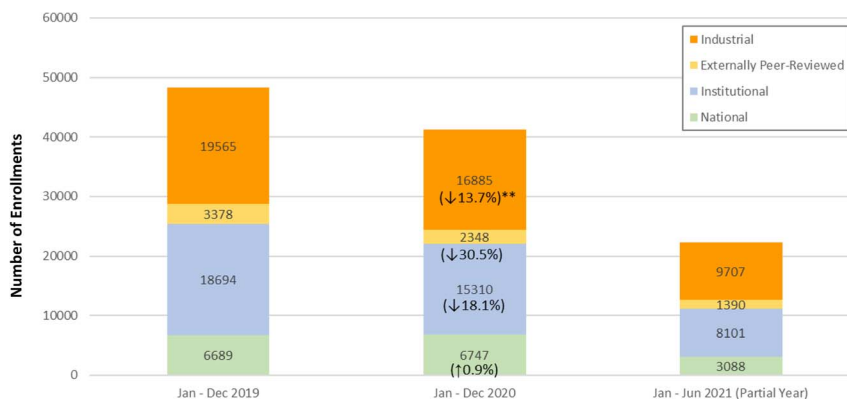


FIGURE 1. Annual enrollment to trials at NCI-Designated Cancer Centers by study source category (see Table 1 for definitions). Includes patients enrolled during each of 3 time periods: January 1, 2019, to December 31, 2019; January 1, 2020, to December 31, 2020; and January 1, 2021, to June 30, 2021 (partial year). The numbers in parentheses reflect percent change in enrollment from 2019 to 2020. Total enrollment to all trials over the entire time period was 111,902 patients.

TABLE 3. Nonindustrial Trials* Monthly Enrollment and Percent Change in Enrollment From 2019 Compared With the Analogous 2020 and 2021 Month†

(A) Nonindustrial Trial Overall Enrollment													
Year	Enrollment (Percent Change Compared With Analogous 2019 Month)												
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Average Monthly
2019	2604	2429	2441	2553	2531	2137	2384	2480	2270	2620	2210	2102	2397
2020	2501 (-4.0)	2380 (-2.0)	2096 (-14.1)	1192 (-53.3)	1318 (-47.9)	1911 (-10.6)	2104 (-11.7)	2173 (-12.4)	2229 (-1.8%)	2307 (-11.9)	2080 (-5.9)	2114 (+0.6)	2034 (-15.1)
2021	2010 (-22.8)	1946 (-19.9)	2312 (-5.3)	2236 (-12.4)	2057 (-18.7)	2018 (-5.6)							2097 (-12.5)
(B) National Trial Enrollment													
Year	Enrollment (Percent Change Compared With Analogous 2019 Month)												
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Average Monthly
2019	573	550	575	628	569	487	536	617	530	611	519	494	557
2020	664 (+15.9)	640 (+16.4)	551 (-4.2)	314 (-50.0)	343 (-39.7)	542 (+11.3)	567 (+5.8)	592 (-4.1)	620 (+17.0)	687 (+12.4)	631 (+21.6)	596 (+20.6)	562 (+0.9)
2021	569 (-0.7)	478 (-13.1)	495 (-13.9)	528 (-15.9)	542 (-4.7)	476 (-2.3)							515 (-7.7)
(C) Externally Peer-Reviewed Trial Enrollment													
Year	Enrollments (Percent Change Compared With Analogous 2019 Month)												
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Average Monthly
2019	319	309	283	306	287	245	288	299	272	283	238	249	282
2020	269 (-15.7)	274 (-11.3)	221 (-21.9)	115 (-62.4)	115 (-59.9)	202 (-17.6)	193 (-33.0)	185 (-38.1)	198 (-27.2)	206 (-27.2)	190 (-20.2)	180 (-27.7)	196 (-30.5)
2021	203 (-30.4)	258 (-34.3)	237 (-8.8)	238 (-22.5)	232 (-17.1)	232 (-5.3)							232 (-17.7)
(D) Institutional Trial Enrollment													
Year	Enrollments (Percent Change Compared With Analogous 2019 Month)												
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Average Monthly
2019	1712	1570	1583	1619	1675	1405	1560	1564	1468	1726	1453	1359	1558
2020	1568 (-8.4)	1466 (-6.6)	1324 (-16.4)	763 (-52.9)	860 (-48.7)	1167 (-16.9)	1344 (-13.8)	1396 (-10.7)	1411 (-3.9)	1414 (-18.1)	1259 (-13.4)	1338 (-1.5)	1276 (-18.1)
2021	1219 (-28.8)	1265 (-19.4)	1559 (-1.5)	1471 (-9.1)	1277 (-23.8)	1310 (-6.8)							1350 (-13.3)

*Includes only enrollment to nonindustrial trials (national, externally peer-reviewed, and institutional).

†Percent change in enrollment from 2019 compared with the analogous 2020 or 2021 month was calculated as the percent of the difference between the 2019 month enrollment and the comparable 2020 or 2021 monthly accrual divided by the 2019 accrual. For example, for nonindustrial trials overall (A) in January 2020, the percent change from 2019 was calculated as 100 [(2604 - 2501)/2604].

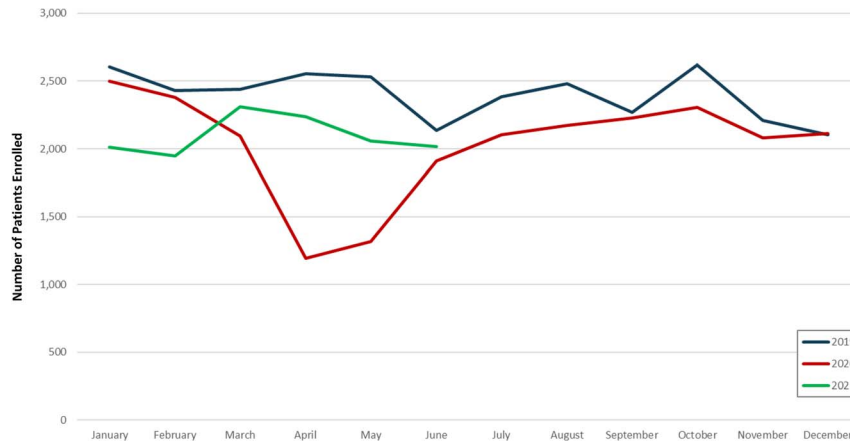


FIGURE 2. Monthly enrollment from January 1, 2019, through June 30, 2021, to NCI-Designated Cancer Center nonindustrial trials (national, externally peer-reviewed, and institutional). Total enrollment to nonindustrial trials over the time period was 65,745 patients.

from one of the NCTN groups support this notion.¹⁰ Patient hesitancy to participate in clinical trials due to concerns for perceived increased risk of COVID-19 exposure may also be a factor.¹¹ We plan to survey the NCI-DCCs to further explore the extent of these issues that may have long-term effects on clinical trials.

The overall decrease in enrollments for 2020 may have been far worse than observed without the rapid implementation of operational flexibilities by the NCI, the NCI-DCCs, and other sponsors with guidance from the FDA. Examples of some of these changes include obtaining signed informed consent remotely, use of telehealth visits for clinical trial safety assessments, conducting study procedures and administration of therapy at local facilities, shipment of oral investigational agents directly to patients and local oncology practices, utilizing remote auditing, and reducing the impact of minor protocol deviations on assessment of clinical trial site performance.¹² The lessons learned during the ongoing pandemic and the rapid acceptance of decentralized clinical trial activities by the community have called for a reexamination of the conduct of cancer clinical trials by academic centers, industry, NCI, and the FDA.¹³ The National Cancer Institute is committed to further

enhancing its clinical trials programs and promoting access to clinical trials. The institute is taking steps toward these goals by implementing the strategic recommendations from NCI's Clinical Trials and Translational Research Advisory Committee that include incorporating some of the adaptations made during the pandemic into standard clinical trial practice, promoting expanded eligibility criteria, and conducting trials that support minority and underserved patient needs.¹⁴

A major strength of our report is that we were able to analyze and aggregate interventional clinical trial data for the entire NCI-DCC program. The National Cancer Institute's Clinical Trials Reporting Program database was deployed in 2009 to serve as a comprehensive repository of information about clinical trials taking place at NCI-DCCs to facilitate clinical trial research portfolio management and scientific planning and support the NCI's Web site (cancer.gov), as well as the NCI Cancer Information Service for finding clinical trials. The CTRP uses consistent terminology and standardized data elements to optimize search and retrieval of cancer clinical trial information, a standard representation of persons and organizations that supports attribution of site enrollment to parent organizations, for example, NCI-DCCs, and serves

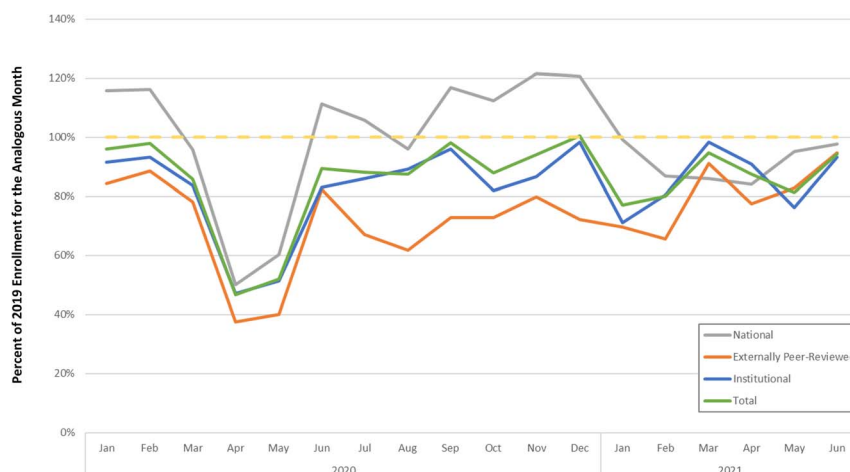


FIGURE 3. Monthly comparison of enrollment to NCI-Designated Cancer Center nonindustrial trials (national, externally peer-reviewed, and institutional). The prepandemic monthly enrollment in 2019 is the baseline, indicated by the yellow dashed line at 100%. Percent of 2019 enrollment was determined by dividing the monthly enrollment number in 2020 and 2021 by the analogous month in 2019. Total enrollment to nonindustrial trials over the time period was 65,745 patients.

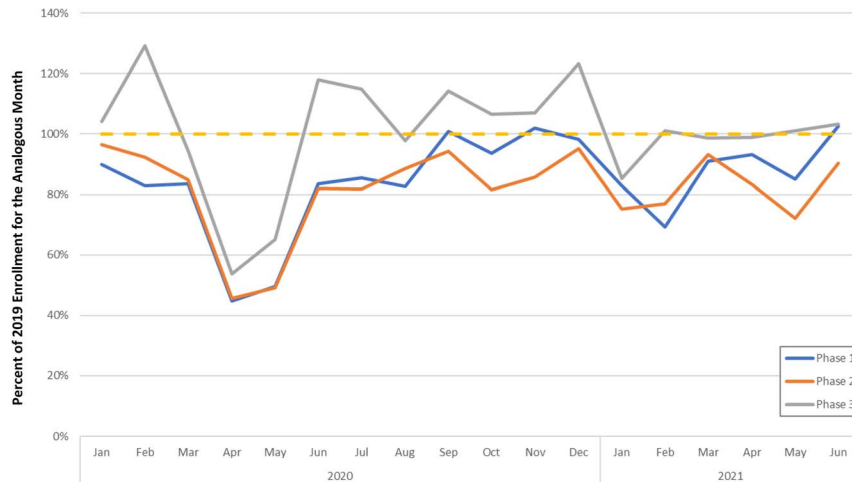


FIGURE 4. Monthly comparison of enrollment to NCI-Designated Cancer Center nonindustrial trials (national, externally peer-reviewed, and institutional). The pre-pandemic monthly enrollment in 2019 is the baseline, indicated by the yellow dashed line at 100%. Percent of 2019 enrollment was determined by dividing the monthly enrollment number in 2020 and 2021 by the analogous month in 2019. Total enrollment for all phases of nonindustrial trials excluding phase N/A over the time period was 62,887 patients.

as the source of trial and enrollment data for P30 Cancer Center Support Grant Data Table 4. These features allow for consistent representation of data within and among NCI-DCCs.

There are several limitations to our report. We included only cancer treatment trials in our analysis; thus, we cannot make conclusions about the effect of the pandemic on enrollment to other types of trials conducted at NCI-DCCs, for example, cancer control and prevention. We did not perform formal statistical analyses or modeling of the data for this initial descriptive review of the data. In addition, the data presented are aggregate and summarize the experience for the cancer centers' program as a whole. The effect of the pandemic on enrollment may have differed at individual centers based on their size, location, policies, and other factors. It is important to point out that there is some month-to-month and annual fluctuation in total enrollments due to a variety of factors including the availability of trials. Thus, using 2019 enrollments as the target benchmark for determining whether enrollments have recovered to prepandemic levels has some limitations.

There is some variability among centers in how they interpret the classification schema for some trial registration data elements, such as trial primary purpose and study source. Although NCI reviews the registration data elements at the time of submission, the NCI-DCC is responsible for the quality of the data submitted and makes the final determination on the coding. Although we have not fully assessed the extent of this inconsistency, it seems to affect nontreatment trials (e.g., cancer control, health services research trials) to a greater extent than treatment trials. In addition, although implausible data values are flagged or rejected at the time of data entry, there is no auditing of source enrollment or demographic data at this time.

Because NCI does not collect the date of patient enrollment for industrial trials, we were unable to assess the monthly enrollment to industrial trials. Furthermore, centers sometimes experience delays in reporting enrollment data such that it is possible that the enrollment to industrial trials occurred in a quarter other than when it was reported. The extent of this is unknown because we cannot confirm enrollment date. Although this may cause inconsistency within a single year, over the course of several years this is not likely to have a major effect.

In conclusion, our analysis indicates that the profound decrease in enrollment to cancer treatment clinical trials in 2020 col-

lectively among NCI-DCCs during the COVID-19 pandemic has not yet fully returned to the 2019 baseline as of mid-2021. This analysis provides an example of how NCI's CTRP data can contribute to our understanding of external perturbations such as the COVID-19 pandemic on clinical trial participation throughout the NCI-DCCs, a major component of the NCI clinical trial system. Possible future analyses related to the ongoing impact of the pandemic and beyond include assessing the trends in activation of cancer clinical trials over time, whether enrollments vary by size and location of centers, and the participation of patient subgroups based on demographic characteristics. The strains on the clinical trial systems due to the pandemic have been substantial, but we are hopeful that some of the changes in clinical trials conduct implemented during the pandemic will become permanent for the trials that NCI supports and help broaden access to trials. Developing policies to realize the full potential of CTRP data as recommended by NCI's Clinical Trials and Translational Research Advisory Committee¹⁵ will also increase the capability of NCI and its stakeholders to monitor the impact these changes on participation in trials throughout NCI's clinical trials programs.

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