

⑧North American Cancer Center Clinical Research Capacity and Benchmarking in the Postpandemic Era

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ABSTRACT

ACCOMPANYING CONTENT

PURPOSE Cancer center clinical trial offices (CCTOs) support trial development, activation, conduct, regulatory adherence, data integrity, and compliance. In 2018, the Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) Steering Committee conducted and published survey results to benchmark North American CCTOs, including trial volume, accrual, full time equivalents (FTEs), and budget. The survey was readministered in 2023 to assess contemporary CCTO performance and capacity with results presented here.

METHODS The 28 question 2023 survey was sent to directors of AACI's clinical member cancer centers. Survey participation was voluntary, no compensation was provided, and data requested covered operations during 2022. Definitions were consistent with National Cancer Institute (NCI) CCTO reporting requirements and AACI staff anonymously compiled results for descriptive statistical reporting.

RESULTS The survey response rate was 61% (60/99). The median annual CCTO budget was \$11.5 million (M) US dollars (USD) versus \$8.2M USD in 2018. These budgets support a median of 150 FTEs versus 104 previously, and a median total of 384 versus 280 interventional treatment trials and a median of 479 versus 531 interventional treatment accruals. Sources of support for CCTO annual budgets were primarily from industry revenue (45.3%) or institutional support (31.7%). Nearly 60% of centers reported activating NCI-sponsored studies within 90 days but only 9% reported meeting a 90-day activation timeline for industry sponsored studies.

CONCLUSION Contemporary benchmarks for CCTO operations through this survey demonstrate larger staff sizes, larger budgets, more trials supported, but fewer patients enrolled to interventional treatment trials in comparison with 2018. These data shine a critical light on the increasing complexity of cancer clinical trials, the importance of external funding sources, and necessary operational efficiency upgrades to provide cutting-edge cancer research and care.

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INTRODUCTION

Cancer centers in North America represent critical engines for the acceleration of cancer treatment advancements, translation of discoveries into the clinic and community, and education of the next generation of physician scientists. Within these centers, the cancer center clinical trials office (CCTO) is the hub of expertise, operations, and safety oversight of human subject clinical research involving patients with cancer engaged in innovative scientific hypothesis-driven testing. This clinical research extends from prevention and early detection through cancer treatment and survivorship. The CCTO is a centralized

organization that supports all aspects of cancer clinical research operations including contracts, budget development and negotiation, billing and finance, regulatory oversight, protocol development and activation, conduct and coordination of clinical trial participants, and data integrity. The CCTO provides investigators with a critical resource for these services along with recruitment, training, and education for the research staff and providers. Centers with National Cancer Institute (NCI) designation are required to additionally have a clinical protocol data management system that provides centralized operational and oversight functions within the cancer center reporting structure and a comprehensive Protocol Review and Monitoring System to

CONTEXT

Key Objective

How have North American Cancer Center Clinical Trial Offices (CCTOs) evolved in size, resources, and staffing after the pandemic and in response to the changing landscape of cancer clinical trials?

Knowledge Generated

In comparison with survey data last obtained in 2018, new survey data in 2023 across 60 centers demonstrate that centers have adapted to more complex clinical trials and increased regulatory oversight requirements by increasing their staff sizes and operational budgets and offering more clinical trials, but with the fewer total patients enrolled to interventional treatment trials.

Relevance

These new benchmarks highlight that operational efficiencies, adoption of new time saving technologies, reduced regulatory redundancies, inclusive eligibility criteria, and lowered barriers to participation are all critical for CCTOs to successfully operate in the future.

ensure the scientific merit of trials and monitor study progress, including accrual monitoring.¹ For patients with cancer, CCTOs serve as the system that allows access to new experimental therapies that are compliant with regulatory requirements and have rigorous safety oversight.

The COVID-19 pandemic significantly disrupted the health care system, health care delivery, and CCTO operations, with an immediate reduction in capacity to conduct cancer clinical research across the United States.² This reduction included significant research staff turnover, delays in trial activation, institutional financial losses, and reduced enrollment. However, it was also accompanied by concurrent improvements in operational efficiencies and innovations, such as the incorporation of telehealth, electronic documentation, and decentralized tools, including electronic consenting and shipping oral drugs, remote monitoring, and novel staff onboarding and educational resources.²

As of 2024, the Association of American Cancer Institutes (AACI) is the professional organization representing 107 leading academic and freestanding cancer research centers across North America. AACI's Clinical Research Innovation (CRI) provides a network for CCTO leaders to share best practices. The first of its kind benchmark survey data were generated by AACI member institutions in 2018.³ The purpose of the original survey was to allow centers to compare their performance and use the data to promote efficient clinical research operations, understand how they compare with peers, and ensure they are appropriately resourced to meet their cancer center clinical trial goals. Given the well-documented impact of the COVID-19 pandemic on CCTO operations, the AACI CRI modernized the original survey with some clarifying questions and updated terms, but otherwise undertook a network-wide assessment to inform contemporary benchmarks and operational capacity of CCTOs in 2023.

METHODS

Participants

The AACI CRI Steering Committee and administrative staff developed the 2023 AACI CRI Benchmarking Survey, hereafter referred to as survey, for electronic distribution. The survey was sent via email to the cancer center directors and administrators at 99 of the 107 AACI academic cancer center members which met the criteria of both providing clinical care and having a CCTO. Eight members are basic science centers which do not meet those criteria. Survey participation was voluntary and available to all cancer center members; no compensation for participation was provided, but centers were offered access to the final data set in exchange for participation.

The survey's purpose was to update data on the capacity and operations of North American CCTOs postpandemic. The survey was distributed via Survey Sparrow on May 17, 2023, with a 3-week timeline for completion. Three reminders and a PDF copy of the survey were sent before the survey closing on June 7, 2023. Five centers received deadline extensions (a few weeks on average) provided by AACI administrators because of various factors.

Design

The survey had 28 questions designed by the CRI Steering Committee (Data Supplement, Appendix S1, online only). Survey questions covered several domains including details on trials conducted, accruals, operations, staff, budget, administration, and leadership. Answer logic was used in the design to minimize the number of questions relative to how a question was answered. Responses used NCI definitions and data reporting guidelines consistent with Cancer Center Support Grant (CCSG) Data Table 4 (survey definitions and data dictionary are presented in the Data Supplement,

Appendix S2). For most questions, annualized data represented either calendar or fiscal year 2022, depending on the question. Institutional review board approval was not deemed necessary given the survey objectives, lack of human subject data collected, and aggregate manner of response reporting. The results were collated by AACI staff, analyzed by an independent team of biostatisticians, and presented in aggregate to maintain the confidentiality of each participating center (a list of survey respondents is presented in the Data Supplement, Appendix S3).

RESULTS

Overall, there was a 61% completion rate (60 of 99 eligible AACI centers). There were no duplicate respondents, and all centers reported data from calendar or fiscal year 2022, depending on the timeframe specified in each question. The types of responding cancer centers were NCI-designated (12%), NCI-designated and comprehensive (70%), and emerging (not currently NCI-designated; 18%). Seven percent characterized themselves as freestanding cancer centers and 93% as academic medical centers. All centers were based in North America (the United States and Canada). **Table 1** summarizes the key characteristics of survey respondents. Compared with the 2018 survey, the relative proportion of participants in the surveys was similar as it

relates to NCI designation (82% v 77%) and from an academic medical center (83% v 87%). Despite adding more AACI members in the interim years, the current survey had a slightly lower overall completion rate compared with 2018 (61% v 86%; 79 of 92 eligible AACI centers).

The annual operating budget for CCTOs ranged between \$2 million (M) US dollars (USD) and \$96M USD with a median of \$11.5M USD (mean \$13.8M USD). Seventy-nine percent of centers reported an annual CCTO budget of <\$19.9M USD. These budgets supported a median total of 433 active interventional trials. Trial numbers varied by CCTO budget categories (<\$4M USD, \$4–9.9M USD, \$10–19.9M USD, \$20–29.9M USD, and ≥\$30M USD) with total interventional trial portfolios median sizes of 309, 290, 418, 695, and 1,083, respectively. For the subset of interventional trials that are classified as treatment, CCTOs had a median number of 384 active interventional treatment trials with median portfolio sizes of 203, 267, 375, 593, and 913 according to the same budget categories (**Table 2**). Compared with the 2018 survey, CCTOs have, in general, increased their annual budgets (median \$11.5M USD v \$8.2M USD) and support more treatment trials (**Table 3**).

The median total accrual across all interventional trials was 1,082 participants with budget categories (<\$4M USD, \$4–

TABLE 1. Cancer Center Survey Respondent Characteristics

Characteristic	All	NCI-Designated	NCI-Designated Comprehensive Center	Not Currently NCI-Designated; Emerging Cancer Center	P
	No. (%)	No. (%)	No. (%)	No. (%)	
Type of centers, N = 60					
Freestanding cancer center	4 (6.67)	0 (0)	4 (9.52)	0 (0)	.741
Academic medical center	56 (93.33)	7 (100)	38 (90.48)	11 (100)	
Budget ranges, N = 60					
<4M	7 (11.67)	0 (0)	3 (7.14)	4 (36.36)	.006
4-9.9M	18 (30)	6 (85.71)	8 (19.05)	4 (36.36)	
10-19.9M	22 (36.67)	1 (14.29)	18 (42.86)	3 (27.27)	
20-29.9M	10 (16.67)	0 (0)	10 (23.81)	0 (0)	
≥30M	3 (5)	0 (0)	3 (7.14)	0 (0)	
FTE ranges, N = 59					
<50	12 (20.34)	2 (28.57)	2 (4.88)	8 (72.73)	<.0001
50-149	18 (30.51)	3 (42.86)	13 (31.71)	2 (18.18)	
150-249	20 (33.9)	2 (28.57)	17 (41.46)	1 (9.09)	
≥250	9 (15.25)	0 (0)	9 (21.95)	0 (0)	
Reportable cancer case ranges, N = 57					
<2,500	9 (15.79)	2 (28.57)	3 (7.5)	4 (40)	.0003
2,500-4,999	22 (38.60)	5 (71.43)	11 (27.5)	6 (60)	
5,000-7,499	13 (22.81)	0 (0)	13 (32.5)	0 (0)	
≥7,500	13 (22.81)	0 (0)	13 (32.5)	0 (0)	

NOTE. P values are obtained from the Fisher exact test within each variable, comparing the counts of each cancer center type: NCI-designated and NCI-designated comprehensive center and not currently NCI-designated; emerging cancer center.

Abbreviations: FTE, full-time equivalent; M, millions; NCI, National Cancer Institute.

TABLE 2. Median Trials, Accrals, and CCTO Staff Supported by Budget

CTO Budget (M), USD	No. of Centers (N = 60)	Median CTO Staff (range)	Median Active Trials (range)	Median Treatment Trials (range)	Median Treatment Accrals (range)
<\$4M USD	7	42 (20-155)	309 (100-672)	203 (0-303)	122 (0-1,302)
\$4M-\$9.9M USD	18	72 (13-444)	290 (53-2967)	267 (48-2529)	300 (0-1,765)
\$10M-\$19.9M USD	22	154 (6-500)	418 (100-842)	375 (150-731)	440 (0-1,948)
\$20M-29.9M USD	10	227 (160-346)	695 (429-1,779)	593 (303-800)	737 (488-1,379)
≥\$30M USD	3	1,265 (250-3,000)	1,083 (1,012-1,517)	913 (846-1,289)	3,637 (790-5,986)

Abbreviations: CCTO, cancer center clinical trial office; M, millions.

9.9M USD, \$10-19.9M USD, \$20-29.9M USD, and ≥\$30M USD) of 330, 919, 1,193, 1,122, and 7,053 participants, respectively. For the subset of interventional treatment trials, the median total accrual was 479 participants with 132, 324, 469, 737, and 3,637, respectively, per budget category. Unlike many other metrics demonstrating upward trajectories from 2018, the current survey demonstrates a moderate reduction in the median accrals per budget category (Table 3).

Of note, the accrual to all interventional treatment trials across all centers was 9.2% of the median center reportable cancer cases as listed in the CCSG data Table 3. The demographic distribution of accrals across all centers in all interventional trials for race and ethnicity was 75.3% White, 10% Black, 5.8% Hispanic or Latino, 5% unknown, 2% Asian, and <1% for both Native American or other Pacific Islander and American Indian or Alaska native. The accrual distribution by sex was 52% female, 47% male, and <1% unknown or not reported. Data related to inclusivity in clinical trial participants were not collected in 2018.

Sources of support for CCTO annual budgets were primarily from industry revenue (45.3%) or institutional resources (31.7%). The majority of centers (75%) reported <50% of their budget from institutional sources. Further breaking down institutional funding sources, 14.4% came from academic institutional funds, 10.2% from clinical institutional funds, and 7.1% from cancer center funds. The percent of total annual CCTO budget that came from external National Institutes of Health (NIH)/NCI grants was 7.1%, state appropriated funds 3.5%, and philanthropy 6.1%. Most (70%) CCTO budgets received <8% of their total annual budget from external grants (eg, NIH, U01, R01, SPORES, etc; Fig 1).

The relative size of the CCTO research staff supported by CCTO budgets differed by NCI designation status (Fig 2 and Table 2). The median number of CCTO staff supported by the CCTO budget was 150 (range of 6-3,000 full time equivalents [FTEs]) which represented an increase from a median of 104 (range of 5-811 FTEs) in 2018. In analyzing staff roles supported by the CCTO budget, the majority of CCTOs support traditional research staff roles, including CTO

administrative director; administrative support; CTO management; Protocol Review Monitoring Committee (PRMC) and ancillary committee administration; registered nurse (RN) and non-RN clinical research coordinators; contracts, budgeting, and cost recovery staff; quality assurance staff; regulatory management staff; training and education staff; research specimen collection staff; clinical trials management application analyst or programmer; and data safety monitoring committee administration. In addition, 42.1% of CCTOs support dedicated trial coverage analysis or billing compliance roles, 38.6% support research pharmacists, 12.3% support statisticians, and 3.5% support a medical ethicist. The Data Supplement (Table S5) displays the distribution of all reported CCTO-supported staff within the center.

Time to trial activation is an important metric for bringing new therapies to patients and completing trials on schedule. The median number of calendar days to open an interventional treatment trial (defined as from PRMC/scientific review committee [SRC] submission to study open to accrual) was shortest for national sponsored studies (eg, NCI-sponsored or NCI clinical trial network trials) at 80 days (range, 3-252). Nearly 60% of centers reported activating national sponsored studies within 90 days. For externally peer reviewed studies, the median time to activation was 151 days (range, 5-328). Industry studies had a median of 170 days (range, 21-311) while institutional studies took the longest with a median of 180 days (range, 9-488). Only 9% of CCTOs reported achieving a 90-day activation timeline for industry sponsored studies (Table 4). The median time to trial activation in 2018 was 167 days (range, 53-322 days) but was not further broken down by trial sponsor type, which is now an appropriate approach.

All CCTOs reported having an inpatient or hospital-based electronic medical record, with 50 centers (83%) using EPIC, eight using Cerner (13%), one Allscripts (1.7%), and one MedConnect (1.7%). For clinical trial management systems, 48 of the 60 cancer centers (80%) use OnCore, an Advarra product. Others reported using Velos (8%), Signal Path (3%), REDCap (1.7%), Research Navigator (1.7%), or a homegrown system (1.7%). Two centers reported using no electronic trial management system (3%). The majority of CCTOs (78%)

TABLE 3. Comparison of Cancer Center Demographics by Survey Year

Comparison of Cancer Center Demographics by Survey Year		2018 (N = 75)	2023 (N = 60)
Survey Years	No. (%)	No. (%)	
Completion rate	75 (86)	60 (61)	
Free-standing	10 (13)	4 (7)	
Academic medical center	65 (87)	56 (93)	
Median budget, USD	\$8.2M USD	\$11.5M USD	
Budget ranges (M = millions), USD			
<\$4M USD	22 (29)	7 (12)	
\$4-\$9.9M USD	25 (33)	18 (30)	
\$10-\$19.9M USD	23 (31)	22 (37)	
\$20-\$29.9M USD	5 (7)	10 (17)	
≥\$30M USD	0 (0)	3 (5)	
No. of active treatment trials, median		1,082	
No. of active treatment trials (ranges by budget), median, USD			
<\$4M USD	197 (31-491)	203 (0-303)	
\$4-\$9.9M USD	282 (113-1,833)	267 (48-2529)	
\$10-\$19.9M USD	366 (63-889)	375 (150-731)	
\$20-\$29.9M USD	549 (298-937)	593 (303-800)	
≥\$30M USD	0	913 (846-1,289)	
No. of treatment accrals, median		479	
No. of treatment accrals (ranges by budget), median, USD			
<\$4M USD	202 (9-2100)	122 (0-1,302)	
\$4-\$9.9M USD	431 (154-4,250)	300 (0-1,765)	
\$10-\$19.9M USD	651 (363-5,214)	440 (0-1,948)	
\$20-\$29.9M USD	1,515 (536-6,351)	737 (488-1,379)	
≥\$30M USD	0	3,637 (790-5,986)	
Median CCTO FTEs supported	104 (5-811)	150 (6-3,000)	
CCTO FTEs supported (range)	N = 75 (%)	N = 59 (%)	
<50	18 (23)	12 (20)	
50-99	18 (23)	9 (15)	
100-149	24 (31)	9 (15)	
≥150	18 (23)	29 (49)	

Abbreviations: CCTO, cancer center clinical trial office; FTE, full time equivalent.

reported using eRegulatory software. The top three platforms used are Florence (34%), Advarra (32%), and Complion (17%). Others include Veeva, Clinical.ly, eREG, e-RED, LabArchives, Sharepoint, Click eIRB, Dropbox, a homegrown system, or a combination of some of these resources. The top platform reported by CCTOs for RECIST measurements was Mint Medical (27%); direct data capture was REDCap (37.5%); electronic research database was REDCap (51%), and investigational drug inventory management was Vestigo (79%).

DISCUSSION

Within cancer centers, the CCTO is charged with developing and coordinating a complex clinical research portfolio that spans a spectrum of research activities involving human

patients with the goal of improving outcomes for patients with cancer while simultaneously advancing the scientific field. The resources required to perform these complex and time-sensitive tasks include a highly expert workforce, financial subsidization, and institutional support. This survey was undertaken to establish a new postpandemic benchmark of the operational characteristics and readiness of cancer clinical research capacity in North America, as the majority of cancer centers involved in cancer clinical research are AACI members.

Table 3 summarizes the key differences in data between the survey in 2018 and now. Despite some variation in questions, survey format, and respondents between the two surveys, we nonetheless observed that CCTOs in 2023 have larger staff sizes, larger budgets, support more trials, but with fewer

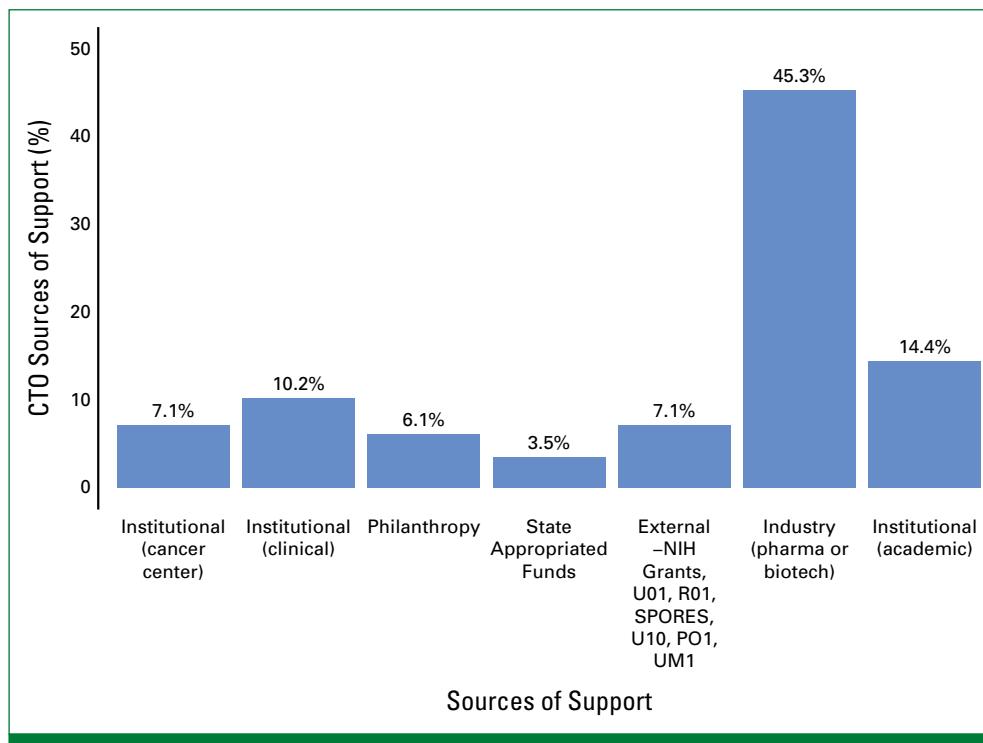


FIG 1. CCTO budget Breakdown by sources of support. The percentages represent the relative share of each category (support sources) within the total FY22 CCTO Budget. Total numbers do not add to 100% because of four centers reported a CCTO budget making up to 6.3% of the total budget, but did not. CCTO, cancer center clinical trial office.

enrollments to interventional treatment trials. This is consistent with the impact seen on CCTO operations due to the pandemic, coupled with the increasing complexity of cancer clinical trials, regulatory requirements, and highly selective eligibility criteria seen in more contemporary

cancer clinical trials.^{4,5} Despite calls for modernization of eligibility criteria to allow more participation in trials and centralized regulatory processes to improve operational efficiencies, our survey data is consistent with other reports that most CCTOs have needed to activate more trials to meet patient needs with lower enrollment goals per trial resulting in larger budgets, more staff, and longer activation times.⁶⁻¹⁰ Such metrics further stress the financial health of CCTOs who rely primarily on external sources of funding to cover costs associated with cancer clinical research. Health care systems and academic institutions provide less than half (closer to one-third) of the budget in support of the CCTO infrastructure, yet these organizations derive the primary benefit of CCTOs. Specifically, clinical trials are essential in

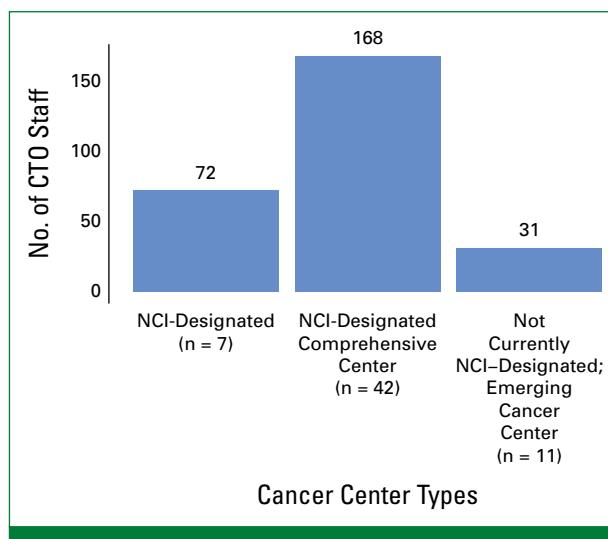


FIG 2. Median CCTO staff by NCI designation. CCTO, cancer center clinical trial office; NCI, National Cancer Institute.

TABLE 4. Days From PRMC/SRC Submission to Open Study Accrual by Trial Type

Group	Average	Median	Range
Externally peer-reviewed	152	151	5-328
Industry	171	170	21-311
Institutional	191	180	9-488
National	90	80	3-252

Abbreviations: PRMC, Protocol Review Monitoring Committee; SRC, Scientific Review Committee.

providing novel therapeutics that drive patient referrals, market differentiation, and ancillary and downstream clinical services revenue and support the academic missions of cutting-edge clinical care, education, and research. Patients seek access to cancer clinical trials to receive cutting edge treatment that would otherwise not be available to them.¹¹ Cancer clinical trials often provide the best treatment option for a patient with a cancer diagnosis and require patient care at the institution providing the clinical trial.¹² On the other side, industry partners are dependent on CCTOs to be able to successfully conduct studies that advance their agents or devices toward a clinical registration and broader population of patients. As demonstrated in our survey, such financial dependency by many CCTOs, with industry support accounting for nearly half of their operational budgets, highlights the need to have safeguards in place against real or perceived financial conflicts of interest.

This analysis is not without limitations that are inherent to the voluntary nature of participation and selection and completion bias. In addition, although the data are aggregated based on relative size and characteristics of the cancer center, nuanced particulars of location (inner city *v* rural community serving institutions) may add variability that could not be captured. Finally, the recovery from the impact of the pandemic may not be complete in some institutions that continue to struggle with hiring or training new research staff or suffer from revenue reductions within their health care system. In modernizing the survey, several questions needed to be adjusted to conform with new CCTO and NCI reporting standards, thus some survey questions do not have clear crosswalks between the old and new versions.

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However, we believe the potential for generalization still exists, as the survey participants are representative of most cancer centers across North America with a reasonable survey response rate.

While this survey serves as a one-time updated snapshot, it can help to level set expectations related to the clinical trial capacity of the participating American and Canadian cancer centers. Additionally, institutions can appropriately resource CCTOs noting their own performance relative to peers and identify opportunities to further improve operational efficiencies related to trial activation and enrollment. The AACI CRI intends to repeat this survey annually to track cancer clinical research capacity and readiness in North America over time and provide near real-time benchmarking for identifying opportunities for national infrastructure investments, policy changes, and appropriate partnership expectations. Partnership with the NCI and other national or global organizations may further refine the analyses and utility of this longitudinal data set. Collaborative data sharing is essential to scientific advancement and enhancing the performance of CCTOs to benefit patients with cancer.

In conclusion, this large multi-institutional survey of CCTOs across North America provides a contemporary baseline for administrative metrics, peer standards, and benchmarking to monitor future progress. This postpandemic snapshot of cancer clinical research readiness and capacity can support ongoing discussions and policies to improve CCTO operational efficiencies, sharing of best practices, and investments in CCTO infrastructure to accelerate the translation of research discoveries to viable treatments for patients with cancer.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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- Manuscript writing:** All authors
- Final approval of manuscript:** All authors
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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

North American Cancer Center Clinical Research Capacity and Benchmarking in the Postpandemic Era

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Astellas Pharma (Inst), Genentech (Inst), Bayer, BioGeneriX, Bristol

Myers Squibb, GORE, Janssen, Gilead Sciences (Inst)

Angela Fritsche

Employment: Mayo Clinic Cancer Center

Uncompensated Relationships: Society for Clinical Research Sites, Oncology Board, Association of American Cancer Institutes

Tara L. Lin

Consulting or Advisory Role: SERVIER, Jazz Pharmaceuticals

Research Funding: Bio-Path Holdings, Inc (Inst), Astellas Pharma (Inst),

Celyad (Inst), Aptevio Therapeutics (Inst), Cleave Biosciences (Inst),

CicloMed (Inst), Jazz Pharmaceuticals (Inst), Cardiff Oncology (Inst),

Kura Oncology (Inst)

Frances Brogan

Employment: Columbia University

Thomas J. George

Consulting or Advisory Role: BillionToOne, Seagen, Nihon Medi-Physics, KAHR Medical, Avammune Therapeutics

Research Funding: Bristol Myers Squibb (Inst), Merck (Inst),

AstraZeneca/MedImmune (Inst), Lilly (Inst), Bayer (Inst), Incyte (Inst),

Ipsen (Inst), Genentech (Inst), Astellas Pharma (Inst), BioMed Valley

Discoveries (Inst), GlaxoSmithKline (Inst), Amgen (Inst), OncoC4 (Inst), BillionToOne (Inst), Jounce Therapeutics (Inst), Elicio Therapeutics (Inst), Seagen (Inst)

Open Payments Link: <https://openpaymentsdata.cms.gov/physician/321938>

No other potential conflicts of interest were reported.