

# Clinical Trial Metrics: The Complexity of Conducting Clinical Trials in North American Cancer Centers

Carrie Lee, MD, MPH<sup>1</sup>; Theresa L. Werner, MD<sup>2</sup>; Allison M. Deal, MS<sup>1</sup>; Cassandra J. Krise-Confair, MPH<sup>3</sup>; Tricia Adrales Bentz, MHA<sup>4</sup>; Theresa M. Cummings, RN, MS<sup>5</sup>; Stefan C. Grant, MBBCh, MD, JD, MBA<sup>6</sup>; Ashley Baker Lee<sup>7</sup>; Jessica Moehle, BS<sup>2</sup>; Kristie Moffett, MHA<sup>8</sup>; Helen Peck, RN, MA<sup>9</sup>; Stephen Williamson, MD<sup>10</sup>; Aleksandar Zafirovski, MBA<sup>11</sup>; Kate Shaw, MA<sup>12</sup>; and Janie K. Hofacker, RN, MS<sup>12</sup>

**QUESTION ASKED:** What are the benchmarks for North American cancer center clinical trial offices (CTOs) with regard to sources of financial support, interventional treatment trial volume, trial activation timelines, accrual by trial sponsor type, full-time equivalents (FTEs), staff turnover, and do these benchmarks vary by National Cancer Institutes (NCI) designation?

**SUMMARY ANSWER:** Trial volumes, accruals, activation timelines, and sources of support varied widely by cancer center size and regional demographics. NCI designation, among those CTOs with a budget of less than \$4 million, was associated with more trials, accruals, and FTEs.

**WHAT WE DID:** An 11-question survey designed by the Association of American Cancer Institutes Clinical Research Innovation steering committee was sent to the cancer center director, administrative director, and CTO administrator at 90 cancer centers in the United States and two in Canada; 72 centers responded. A dictionary of terms was included to standardize survey responses. For data collection consistency, cancer centers were asked to report interventional treatment clinical trial activity for 12 months after 2016 and to use the same period for all survey questions.

**WHAT WE FOUND:** The number of FTE employees working within the CTOs ranged from 4.5 to 811; the median was 104. The median number of analytic cases (ie, newly diagnosed or received first course of treatment) reported by the main center was 3,856. Annual CTO budgets ranged from \$250,000 to \$23,900,000 (median, \$8.2 million). The median trial

activation time, based on 61 centers, was 167 days. Median accruals per center was 480 (range, 5-6,271) and the median number of trials per center was 282 (range, 31-1,833). Budget and FTE ranges varied by NCI designation. Estimating on the basis of benchmark data, the accrual to trial ratio was 1.5, median accrual to FTE ratio was 5, and median cost per accrual was \$17,363.

**BIAS, CONFOUNDING FACTORS, DRAWBACKS:** A wide range in each of the outcomes was noted, in keeping with the wide variation in size and scope of cancer center CTOs across the United States and Canada. These variations may warrant additional investigation. Among the smaller centers (CTO budget < \$4 million), there was an association between a larger number of trials, accruals, FTEs, and NCI designation. This finding is hypothesis generating; it cannot be concluded that the relationship is causal and reveals the need for more investigation of the value of NCI designation and its impact on CTO operations and support.

**REAL-LIFE IMPLICATIONS:** Transparent sharing of these benchmark data are essential for helping centers determine if their offices are “right sized” for their accrual goals and for justifying the cost of oncology clinical trials. The data may be used as a baseline for cancer centers to collectively develop solutions, such as how to systematically address the gap between trial selection and trial accrual (ie, improve the accrual-to-trial ratio) and how to more collaboratively address the problems of slow activation and underfunded trials.

## CORRESPONDING AUTHOR

Carrie Lee, MD, MPH, UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Physicians Office Building, 3rd Fl, 170 Manning Dr, CB# 7305, Chapel Hill, NC, 27599; e-mail:carrie\_lee@med.unc.edu.

## ASSOCIATED CONTENT

See accompanying editorial on page 1

### Appendix

Author affiliations and disclosures are available with the complete article at [ascopubs.org/journal/op](https://ascopubs.org/journal/op).

Accepted on September 22, 2020 and published at [ascopubs.org/journal/op](https://ascopubs.org/journal/op) on November 13, 2020: DOI <https://doi.org/10.1200/OP.20.00501>

# Clinical Trial Metrics: The Complexity of Conducting Clinical Trials in North American Cancer Centers

Carrie Lee, MD, MPH<sup>1</sup>; Theresa L. Werner, MD<sup>2</sup>; Allison M. Deal, MS<sup>1</sup>; Cassandra J. Krise-Confair, MPH<sup>3</sup>; Tricia Adrales Bentz, MHA<sup>4</sup>; Theresa M. Cummings, RN, MS<sup>5</sup>; Stefan C. Grant, MBBCh, MD, JD, MBA<sup>6</sup>; Ashley Baker Lee<sup>7</sup>; Jessica Moehle, BS<sup>2</sup>; Kristie Moffett, MHA<sup>8</sup>; Helen Peck, RN, MA<sup>9</sup>; Stephen Williamson, MD<sup>10</sup>; Aleksandar Zafirovski, MBA<sup>11</sup>; Kate Shaw, MA<sup>12</sup>; and Janie K. Hofacker, RN, MS<sup>12</sup>

## abstract

**PURPOSE** Cancer clinical trials offices (CTOs) support the investigation of cancer prevention, early detection, and treatment at cancer centers across North America. CTOs are a centralized resource for clinical trial conduct and typically use research staff with expertise in four functional areas of clinical research: finance, regulatory, clinical, and data operations. To our knowledge, there are no publicly available benchmark data sets that characterize the size, cost, volume, and efficiency of these offices, nor whether the metrics differ by National Cancer Institute (NCI) designation. The Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) steering committee developed a survey to address this knowledge gap.

**METHODS** An 11-question survey that addressed CTO budget, accrual and trial volume, full-time equivalents (FTEs), staff turnover, and activation timelines was developed by the AACI CRI steering committee and sent to 92 academic cancer research centers in North America (n = 90 in the United States; n = 2 in Canada), with 79 respondents completing the survey (86% completion rate).

**RESULTS** The number of FTE employees working in the CTOs ranged from 4.5 to 811 (median, 104). The median number of analytic cases (ie, newly diagnosed or received first course of treatment) reported by the main center was 3,856. Annual CTO budgets ranged from \$250,000 to \$23,900,000 (median, \$8.2 million). The median trial activation time, based on 61 centers, was 167 days. The median number of accruals per center was 480 (range, 5-6,271) and median number of trials per center was 282 (range, 31-1,833). Budget and FTE ranges varied by NCI designation.

**CONCLUSION** The response rate to the survey was high. These data will allow cancer centers to evaluate their CTO infrastructure, funding, portfolio, and/or accrual goals as compared with peers. A wide range in each of the outcomes was noted, in keeping with the wide variation in size and scope of cancer center CTOs across the United States and Canada. These variations may warrant additional investigation.

JCO Oncol Pract 17:e77-e93. © 2020 by American Society of Clinical Oncology

Creative Commons Attribution Non-Commercial No Derivatives 4.0 License 

## INTRODUCTION

Cancer clinical trials play a crucial role in prevention, early detection, cancer treatment, and, ultimately, cancer cures. The vast majority of academic cancer centers that support a large number of clinical trials include a clinical trials office (CTO) in their organizational structure. CTOs are centralized offices that support the various pillars of clinical trial conduct (eg, finance, regulatory, clinical, and data management). A CTO is not required to open clinical trials, but centralized infrastructure allows investigators to focus more on novel science rather than personnel management and ensures that gaps in research staffing

are covered by a shared resource. National Cancer Institute (NCI) designation requires that centers establish a clinical protocol and data management system that provide centralized management and oversight of functions for coordinating, facilitating, and reporting on the cancer clinical trials of the institution.

It is widely acknowledged that the execution of clinical trials is fraught with challenges, including administrative burdens, staffing barriers, regulatory constraints, rising costs, and low patient accrual. An NCI-ASCO Trial Accrual Symposium concluded there was a need for sites to benchmark and monitor their accrual performance against similar sites to realistically

Author affiliations and support information (if applicable) appear at the end of this article.

Accepted on September 22, 2020 and published at [ascopubs.org/journal/op](https://ascopubs.org/journal/op) on November 13, 2020: DOI <https://doi.org/10.1200/OP.20.00501>

plan for staffing, workload, and number and complexity of trials.<sup>1,2</sup> A National Comprehensive Cancer Network (NCCN) Clinical Research Benchmarking Survey has been conducted six times over the past 12 years in an effort to develop best practices for conducting the most effective and efficient clinical trials for patients with cancer. However, the survey results are only available to NCCN members. There are no large, publicly available benchmark data sets that characterize the volume of work involved in cancer clinical trials, the costs and funding sources to support this work, the time to achieve clinical trial activation, or the workforce characteristics necessary to carry out clinical trial activities.

The Association of American Cancer Institutes (AACI) comprises 102 of the leading academic and freestanding cancer research centers in North America. AACI advances the objectives of cancer centers by facilitating interaction among the centers, educating policymakers,<sup>3</sup> and fostering partnerships between cancer centers and other cancer organizations to improve cancer care. The AACI Clinical Research Innovation (CRI) was established as an AACI initiative in 2009 to address the shared administrative challenges in clinical trial conduct. CRI is guided by a member-elected steering committee. Steering committee members are cancer center CTO medical directors and administrators who represent the various pillars of clinical trial conduct.

The objective of AACI and the CRI steering committee was to develop and widely disseminate a benchmarking survey to allow centers to compare their performance and use the data to promote efficient clinical research operations. These practical data can help CTOs better understand how they compare with peers and if they are “right-sized” and appropriately funded to meet their cancer center clinical trial goals.

## METHODS

### Participants

At the time of the survey, AACI consisted of 98 academic cancer center members. The survey was distributed to 90 centers in the United States and two in Canada that provide clinical care and have a CTO. Of the six centers that did not receive the survey, five are basic science research centers and do not provide clinical care or have a CTO, and one center was newly established and not treating patients at the time of the survey. For consistency of data collection, the cancer centers were asked to report interventional treatment clinical trial activity for a 12-month period after 2016 and to use the same period for all survey questions. Centers could determine a consistent 12-month reporting period to allow for flexibility of reporting according to their institutional standards (ie, calendar or fiscal year). On May 1, 2018, the survey was sent to the cancer center director, administrative director, and CTO administrative director of these 92 AACI cancer centers. Nonresponders were sent three reminder e-mails. There was no incentive for participation. The survey closed on January 15, 2019.

### Design

The 11-question survey was crafted using Qualtrics assessment software (Salt Lake City, UT). Questions were designed by the AACI CRI steering committee; Institutional review board (IRB) approval was not deemed necessary given the survey objectives. The survey addressed cancer center demographics, CTO sources of financial support, interventional treatment trial volume, accrual by trial sponsor type, and staff turnover. To standardize survey answers, a dictionary of terms was included (Appendices A and B). The term “matrix” refers to a cancer center that is intertwined with and dependent on a university structure. Freestanding cancer centers are entities unto themselves and not part of a larger organization.

Interventional treatment trials were defined using the following NCI definition: trials designed to evaluate one or more interventions for treating a disease, syndrome, or condition. A standardized definition was used to enhance validity of responses; the NCI definition was chosen given site familiarity with this definition for reporting to ClinicalTrials.gov and NCI funding opportunities. All centers reported budget data in US dollars; the two Canadian centers converted budget data to US dollars using the applicable exchange rate.

Categories and definitions of funding sources were as follows: national: NCI National Clinical Trials Network or other NCI/National Institutes of Health (NIH)-supported national trial networks; industry: pharmaceutical company-controlled trial design and implementation; externally peer-reviewed: supported by the NIH or by organizations with a peer-review funding system (eg, R01, SP0RE, U01, U10, P01, CTEP); institutional: in-house clinical research study conceptualized, designed, and implemented by cancer center investigators with scientific peer review provided solely by the protocol review and monitoring system of the cancer center; industry or other entities may provide support (eg, drug, device, other funding), but the trial should be the intellectual product of the center investigator.

In addition, information was sought on the number of analytic cases (defined as newly diagnosed or receiving first course of treatment at the center as reported by their tumor registry) reported by the main cancer center and sites outside of the main center.

Trial activation data were measured in calendar days and collected as time intervals between activation milestones, including receipt of protocol to approval by scientific review committee (SRC)/protocol review committee (PRC); SRC/PRC approval to IRB approval; IRB approval to study activation date (when consent to enroll participants is released); contract draft receipt to execution; SRC/PRC approval to first patient accrued; and from initial budget review to budget approval by sponsor. To best estimate the overall activation time, we added the time from (1) receipt of protocol to SRC/PRC approval to (2) SRC/PRC approval to

IRB approval to (3) the time from IRB approval to study activation, with the caveat that this may overestimate the time because some centers submit to PRC and IRB simultaneously. The number of full-time equivalent (FTE) positions supported by the CTO budget included approved vacancies.

Descriptive statistics, including medians and ranges, are provided for survey responses. Differences between centers, based on NCI designation, are compared using the Fisher exact test. For each center, the percentage of its total annual budget that came from each source was calculated. Then the median and range of this number across all centers were reported. Accrual to FTE ratio was calculated by median accrual/FTE and rounded to the nearest whole number. The accrual-to-trial ratio was calculated by median accrual/trial (all sponsors). Institutional funds included school of medicine, central university, health system, investigator-initiated trial support, philanthropic, and state-appropriated funds. The correlation between time to activation and number of accruals was estimated using the Spearman correlation coefficient. Analyses were performed using SAS statistical software, version 9.4 (SAS Institute, Cary, NC).

## RESULTS

Of the 92 eligible AACI centers, 79 (86%) completed the survey. There were no duplicate responders. All centers reported on a 12-month period between January 2016 and July 2017. Survey participant demographics and geographic distribution are shown in [Table 1](#).

### Characteristics of Survey Participants

Approximately three-quarters of responding centers (77%) were NCI designated ([Appendix C](#)). Of the NCI-designated responding centers, 85% were matrix type. There were no significant differences in NCI designation by geographic location of responding centers ( $P = .72$ ).

### Analytic Cases

The median number of analytic cases reported by the main center was 3,856 (range, 635-22,255).

### Budget Range and Budget Sources

Annual CTO budgets ranged from \$250,000 to \$23,900,000; the median was \$8.2 million. The number of centers in each budget category is shown in [Table 1](#). Fifty-eight of the 75 responding centers had an annual CTO budget of < \$12 million. The median number of trials and accruals for centers within each budget range is shown in [Table 2](#). Twenty-one cancer centers had a CTO budget range of \$8-12 million, the median number of trials supported within this budget range was 245, and the median number of accruals to these trials was 498. Seventy-six percent of non-NCI centers had budgets < \$4 million versus NCI centers, which had sites operating in all budget ranges ( $P = .0002$ ). For each center, the percentage of total

annual CTO budget from each source was calculated, and the median of this number across all centers is described ([Table 3](#)). The largest percentage of total annual CTO budget source came from industry-sponsored clinical trials (45%; range, 0%-96%), followed by institutional (40%; range, 0%-100%), national cooperative group (4%; range, 0%-31%), and external (3%; range, 0%-36%). The NCI Cancer Center Support Grant accounted for 2% (range, 0%-24%) of annual CTO budget. Seventy-six percent had  $\geq 23\%$  of their funding from institutional sources. Seventy-five percent of all centers had < 7% of their annual budget come from national cooperative group sources.

### Accrual and Trial Volume

The centers reported 55,573 accruals to 27,493 trials over a 12-month period. The median number of accruals per center was 480 (range, 5-6271) and the median number of trials per center was 282 (range, 31-1833). Median accruals per trial (all sponsors) was 1.5 (range, 0.2-26.6). The estimated ratio of median accrual to FTE was five.

The median percentage of trials, accruals, and annual CTO budget that came from each sponsor type were as follows: industry: 43% trials, 39% accruals, 45% budget; institutional: 15% trials, 33% accruals, 0% budget; national cooperative group: 33% trials, 19% accruals, 4% budget; and external: 4% trials, 5% accruals, 3% budget.

Clinical trial activity primarily took place at the main cancer center versus network (ie, all other) sites. Respondents reported a median of 282 (range, 31-1,833) interventional treatment trials open at the main cancer center. The same centers reported a median of 22 (range, 0-710) trials open at a network site. Of the trials open at a network site, most were sponsored by national cooperative groups.

### CTO FTEs

The number of FTE workers housed within the CTOs ranged from 4.5 to 811 FTEs (median, 104). Of non-NCI designated centers, 71% had < 50 FTEs compared with 10% of NCI-designated centers ( $P < .0001$ ; [Table 1](#)). The median numbers of CTO FTEs at NCI-designated centers and non-NCI-designated centers were 114 and 33, respectively. Twenty-four cancer center CTOs reported 100-149 FTEs. Twenty of these centers were NCI designated, three were not designated, and one was a Canadian center. Eighteen centers had  $\geq 150$  FTEs, all but one, a Canadian center, were NCI designated. FTEs by budget range are shown in [Table 2](#). The median number of FTE workers brought on in a 12-month period was 22 (range, 0-216). The median number of vacancies was 6.5 (range, 0-89).

### Activation Timelines

The median time from receipt of the protocol to SRC/PRC approval was 36 days (range, 7-140 days). The median time from SRC/PRC approval to IRB approval was 58 days (range,

**TABLE 1.** Demographics of Cancer Center Benchmarking Survey Participants

Characteristics of the Cancer Centers by Type	All <sup>a</sup>		NCI Designated (n = 59; 77%)		Not NCI Designated (n = 18; 23%)		P
	No.	%	No.	%	No.	%	
Matrix	67	87	50	85	17	94	.44
Freestanding	10	13	9	15	1	6	
Region							
Canada <sup>a</sup>	2	2.50	n/a	n/a	n/a	n/a	
Midwest	18	22.80	13	22	5	28	.72
Northeast	19	24.10	14	24	5	28	
South	24	30.40	18	30	6	33	
West	16	20.30	14	24	2	11	
Budget range, millions (n = 75)							
< 4	22	29.30	9	16	13	76	.0002
4-7.9	15	20.00	13	23	2	12	
8-11.9	21	28.00	18	32	2	12	
12-15.9	8	10.70	8	14	0	0	
≥ 16	9	12.00	8	14	0	0	
FTE range (n = 78)							
< 50	18	23.10	6	10	12	71	< .0001
50-99	18	23.10	16	27	2	12	
100-149	24	30.80	20	34	3	18	
≥ 150	18	23.10	17	29	0	0	

Note: The number of responding centers varies based on responses provided.

Abbreviations: FTE, full-time equivalents; n/a, not applicable; NCI, National Cancer Institute.

<sup>a</sup>Canadian cancer centers are not eligible to participate in the National Institutes of Health's Funding Opportunity Announcement, which supports NCI-Designated Cancer Centers, and have been excluded from those categories. (Note: the numbers from the NCI/non-NCI Cancer center cells do not add up to the total number in the All columns.)

0-195 days). The median time from full IRB approval to study activation (participants may be consented) was 55 days (range, 1-270 days). The median time from receipt of draft contract to execution was 94 days (range, 14-283 days). The median time from SRC/PRC approval to first patient accrued was 167 days (range, 14-327 days).

The median activation time, based on 61 centers, was 167 days (range, 53-322 days). There was no significant difference in activation times by NCI designation (median

NCI designation v non-NCI designation: 166 v 167 days;  $P = .64$ ) or budget ranges ( $P = .9$ ). Increased time was associated with decreased accruals (Spearman correlation coefficient,  $-0.21$ ).

### Impact of NCI Designation

Of the 22 centers with a CTO budget of < 4 million (n = 13 NCI centers; n = 9 non-NCI-designated centers), the median number of trials at NCI centers was 358 (range,

**TABLE 2.** Median Number of Trials and Accruals for Centers Within Each Budget Range

CTO Budget (millions)	No. of Centers (N = 75)	Trials	Accruals	FTE Workers	Median FTE Workers Hired
< \$4	22	198 (31-491)	182 (5-2,100)	34 (5-125)	8 (0-68)
\$4-\$8	15	307 (128-1,833)	390 (154-3,801)	74 (41-424)	14 (5-137)
\$8-\$12	21	245 (63-739)	498 (239-1,377)	122 (24-197)	25 (7-108)
\$12-\$16	8	394 (173-710)	551 (491-1,931)	123 (77-227)	27 (1-81)
> \$16	9	549 (255-937)	1,272 (536-6,271)	215 (119-811)	58 (24-216)

NOTE. Data are reported as median (range) unless otherwise indicated.

Abbreviations: CTO, clinical trial office; FTE, full-time equivalent.



**TABLE 3.** Total Annual Budget Sources

Budget Source (N = 72)	Median % of Budget (range)
Institutional	40 (0-100)
Industry	45 (0-96)
External	3 (0-36)
National cooperative group	4 (0-31)
Cancer Center Support Grant	2 (0-24)

95-491) versus 137 for non-NCI centers (range, 31-269;  $P = .01$ ). The median number of accruals was 289 for NCI (range, 138-925) versus 96 for non-NCI centers (range, 5-2,100;  $P = .02$ ). The median number of FTEs was 60 for NCI (range, 28-125) versus 25 for non-NCI centers (range, 5-535;  $P = .01$ ). There was no significant difference by NCI designation in the number of new FTE workers hired (NCI v non-NCI center: 13 v 8 FTE workers;  $P = .24$ ).

## DISCUSSION

Cancer centers are hungry for data to help them better understand the business of clinical trials and how they compare with peer institutions. The landscape of clinical trials has changed dramatically over the past decade.<sup>4,5</sup> In years past, large clinical trials with broad eligibility criteria and minimal fresh-tissue requirements were the norm. Today, clinical trials are increasingly multifaceted in design, with complex tissue sampling and molecular and processing requirements. These trials, particularly those involving biologics, are subject to higher levels of regulatory monitoring due to increased risk and complexity. CTO leaders strive to maintain past levels of productivity (measured by trials and accruals) in this highly specialized environment, a task further complicated by the expectation of rapid trial activation, high clinical research staff turnover rates due to industry competition, and the intent to reach more patients in rural and underserved areas. These elements are essential to cancer care delivery but are costly and push the boundaries of adequate clinical trial oversight.

The median CTO budget was \$8.2 million, but there was wide variation (range, \$250,000-\$23,900,000). The majority of CTOs had budgets of < \$12 million. Industry-funded trials accounted for a similar percentage of all trials, accruals, and budget source (43% trials, 39% accruals, 45% budget). We observed that institution-sponsored trials accounted for 15% of trials and 33% of accruals; this is in keeping with greater emphasis on accruals to investigator-initiated, home-grown science as comprehensive cancer centers share in this mission. In addition, cooperative group trials and externally funded trials demonstrate a tremendous gap in trials and accruals relative to budget support. These trials have long been woefully underfunded. Cancer centers must offset the cost

of running these trials with other industry-funded trials and budget sources.

Estimating based on the benchmark data, the median accrual-to-FTE ratio was five and the median cost per accrual was \$17,363. These metrics have plagued CTO administrative directors because organizational leaders often correlate them with operational efficiency. However, that notion is oversimplified because the ratio includes all CTO staff required to support an accrual, not just the enrolling coordinator. The benchmark data support the expansion of CTOs and the commensurate increase in financial support needed to manage the work; it truly takes a village. Health care systems have been reluctant to support clinical research,<sup>6,7</sup> given the cost and the difficult-to-quantify return on investment, but clinical trials are essential to fulfilling an institution's academic mission and attracting patients to centers for cutting-edge care, which, in turn, supports the health care system.

The accrual-to-trial ratio was 1.5. This number highlights the challenge of efficiently using resources. Much time and effort are required to run a clinical trial. Opening trials with little accrual potential places financial strain on a center and has negative implications for sponsors and patients. The cancer community can address this pitfall in many ways; for example, by designing trials to be more inclusive while maintaining patient safety. Broadening eligibility criteria can be done without compromising safety or efficacy, specifically in relation to patients with treated brain metastases, well-controlled HIV, and prior or concurrent malignancies.<sup>2</sup> Selecting trials with high accrual potential and that reflect the populations they serve is also challenging. Using technology, including electronic health records, search engines, and artificial intelligence, holds promise. Careful trial selection and performance monitoring is necessary given the high cost of maintaining low-accruing trials.

Median activation time, based on 61 centers, was 167 days. Increased time was associated with lower accruals, which supports the finding that prolonged activation undermines accrual potential.<sup>3</sup> Reasons for slow activation include budget and contract negotiation, regulatory start-up processes, PRC review, and IRB review.<sup>1</sup> True critical-path analyses are important for mapping the activation timeline, identifying rate-limiting steps, and determining the highest-yield intervention points.

Staff turnover is an ongoing challenge for CTOs. The median number of FTE workers brought in over a 12-month period was 22. The median number of vacancies was 6.5. Unfortunately, turnover begets turnover as loss of experienced staff translates into extra work and job dissatisfaction for those remaining. Reasons for turnover include competition from CROs or industry, lack of career growth opportunities, professional school, heavy workload, poor fit, and normal life events. Strategies to mitigate turnover

include comprehensive orientation for new staff and continuing education; competitive salary; career development; flexible and remote work options, including job sharing; leadership and management training; support for wellness; role clarity; work-life balance; and positive office culture.

Among the smaller centers (CTO budget < \$4 million), there was an association between a larger number of trials, accruals, FTEs, and NCI designation. This finding is hypothesis generating; it cannot be concluded that the relationship is causal. AACI provides support to centers considering and in pursuit of NCI designation; deeper understanding of this relationship and the value of NCI designation warrants more investigation.

## AFFILIATIONS

<sup>1</sup>UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, NC

<sup>2</sup>Huntsman Cancer Institute, University of Utah, Salt Lake City, UT

<sup>3</sup>Starzl Network for Excellence in Pediatric Transplantation, Pittsburgh, PA

<sup>4</sup>Hollings Cancer Center, Medical University of South Carolina, Charleston, SC

<sup>5</sup>University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center, Baltimore, MD

<sup>6</sup>Wake Forest University Baptist Comprehensive Cancer, Winston Salem, NC

<sup>7</sup>City of Hope Comprehensive Cancer Center, Duarte, CA

<sup>8</sup>Moffitt Cancer Center, Tampa, FL

<sup>9</sup>Wilmut Cancer Institute, University of Rochester Medical Center, Rochester, NY

<sup>10</sup>University of Kansas Cancer Center, Kansas City, KS

<sup>11</sup>Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago, IL

<sup>12</sup>Association of American Cancer Institutes, Pittsburgh, PA

## CORRESPONDING AUTHOR

Carrie Lee, MD, MPH, UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Physicians Office Building,

Transparent sharing of these benchmark data are essential for helping centers determine if their offices are “right-sized” for their accrual goals and for justifying the cost of oncology clinical trials. The data may also assist smaller centers in understanding the associations between clinical trial metrics and NCI designation. They shine a light on common problems and may be used as a baseline for cancer centers to collectively develop solutions, such as how to systematically address the gap between trial selection and trial accrual (ie, improve the accrual-to-trial ratio) and how to more collaboratively address the problem of slow activation and underfunded trials to ultimately benefit patients with cancer.<sup>8,9</sup>

3rd Fl, 170 Manning Dr, CB# 7305, Chapel Hill, NC, 27599; e-mail: [carrie\\_lee@med.unc.edu](mailto:carrie_lee@med.unc.edu).

## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at DOI <https://doi.org/10.1200/JOP.20.00501>.

## AUTHOR CONTRIBUTIONS

**Conception and design:** Carrie Lee, Allison M. Deal, Cassandra J. Krise-Confair, Tricia Adrales Bentz, Jessica Moehle, Kristie Moffett, Helen Peck, Stephen Williamson, Aleksandar Zafirovski, Janie K. Hofacker

**Administrative support:** Cassandra Krise-Confair, Tricia Bentz, Ashley Baker Lee, Jessica Moehle, Kate Shaw, Janie K. Hofacker

**Provision of study material or patients:** Stephen Williamson

**Collection and assembly of data:** Carrie Lee, Cassandra J. Krise-Confair, Tricia Adrales Bentz, Theresa M. Cummings, Ashley Baker Lee, Jessica Moehle, Stephen Williamson, Kate Shaw, Janie K. Hofacker

**Data analysis and interpretation:** Carrie Lee, Theresa L. Werner, Allison M. Deal, Cassandra J. Krise-Confair, Theresa M. Cummings, Stefan C. Grant, Helen Peck, Stephen Williamson

**Manuscript writing:** All author

**Final approval of manuscript:** All author

**Accountable for all aspects of the work:** All author

## REFERENCES

- Vose JM, Levit LA, Hurley P, et al: Addressing administrative and regulatory burden in cancer clinical trials: Summary of a stakeholder survey and workshop hosted by the American Society of Clinical Oncology and the Association of American Cancer Institutes. *J Clin Oncol* 34:3796-3802, 2016
- Denicoff AM, McCaskill-Stevens W, Grubbs SS, et al: The National Cancer Institute–American Society of Clinical Oncology Cancer Trial Accrual Symposium: Summary and recommendations. *J Oncol Pract* 9:267-276, 2013
- Bennett CL, Stinson TJ, Vogel V, et al: Evaluating the financial impact of clinical trials in oncology: Results from a pilot study from the Association of American Cancer Institutes/Northwestern University clinical trials costs and charges project. *J Clin Oncol* 18:2805-2810, 2000
- Kim ES, Bruinooge SS, Roberts S, et al: Broadening eligibility criteria to make clinical trials more representative: American Society of Clinical Oncology and Friends of Cancer Research joint research statement. *J Clin Oncol* 35:3737-3744, 2017
- Dilts DM, Cheng SK, Crites JS, et al: Phase III clinical trial development: A process of chutes and ladders. *Clin Cancer Res* 16:5381-5389, 2010
- Cheng SK, Dietrich MS, Dilts DM: A sense of urgency: Evaluating the link between clinical trial development time and the accrual performance of cancer therapy evaluation program (NCI-CTEP) sponsored studies. *Clin Cancer Res* 16:5557-5563, 2010
- Cosgrove DM, Fisher M, Gabow P, et al: Ten strategies to lower costs, improve quality, and engage patients: The view from leading health system CEOs. *Health Aff (Millwood)* 32:321-327, 2013
- Alfano CM, Mayer DK, Beckjord E, et al: Mending disconnects in cancer care: setting an agenda for research, practice and policy. *JCO Clin Cancer Inform* 4: 539-546, 2020
- Baer AR, Zon R, Devine S, et al: The clinical research team. *J Oncol Pract* 7:188-192, 2011

## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

### Clinical Trial Metrics: The Complexity of Conducting Clinical Trials in North American Cancer Centers

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated unless otherwise noted. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to [www.asco.org/rwc](http://www.asco.org/rwc) or [ascopubs.org/op/authors/author-center](http://ascopubs.org/op/authors/author-center).

Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians ([Open Payments](#)).

#### Carrie Lee

**Consulting or Advisory Role:** Delcath Systems

#### Theresa L. Werner

**Research Funding:** AbbVie (Inst), Roche (Inst), Mirati Therapeutics (Inst), Tesaro (Inst), Clovis Oncology (Inst), AstraZeneca (Inst), Genmab (Inst), Mersana (Inst)

#### Stefan C. Grant

**Employment:** TheraBionic

**Leadership:** TheraBionic

**Stock and Other Ownership Interests:** TheraBionic

**Research Funding:** Genentech Mypath (Inst), Loxo (Inst), Bristol Myers Squibb (Inst), Rafael Pharmaceuticals (Inst), Guardant Health

**Travel, Accommodations, Expenses:** Florence Healthcare

#### Ashley Baker Lee

**Consulting or Advisory Role:** 21st Century Medicine (I), Critical Care Research (I), Abbott (I)

**Research Funding:** 21st Century Medicine (I), Critical Care Medicine (I), Abbott (I)

#### Helen Peck

**Consulting or Advisory Role:** International Journal of Radiation Oncology Biology Physics (I)

**Other Relationship:** American Society for Radiation Oncology (I)

#### Stephen Williamson

**Research Funding:** Daiichi Sankyo (Inst), Bayer Health (Inst), Acceleron Pharma (Inst), Sotio (Inst), Rogosin Institute (Inst), Pharmacyclics (Inst), Merck Serono (Inst), EMD Serono (Inst), Sanofi (Inst), Novartis (Inst), Nektar (Inst), Seattle Genetics (Inst), Astellas Pharma (Inst), Aleon Pharma (Inst), Bristol Myers Squibb (Inst), Regeneron (Inst)

**Open Payments Link:** <https://openpaymentsdata.cms.gov/physician/1092063/summary>

No other potential conflicts of interest were reported.



## APPENDIX A: 2018 BENCHMARKING SURVEY

### Association of American Cancer Institutes (AACI) Clinical Research Initiative Benchmarking Survey

#### Survey

#### AACI Clinical Research Initiative Benchmarking Survey

The AACI CRI Steering Committee is inviting your cancer center to participate in a survey to learn more about cancer center clinical trials office (CTO) workload, structure and staffing, trial activation timeline, and sources of CTO funding support. The purpose of collecting this information is to allow cancer center members to compare their center with other AACI member centers.

To assist with standardizing answers for the survey, we have created a [data dictionary](#) of terms used in this survey and these terms are inbedded in the questions.

For questions asking about CTO workload, we are asking respondents to report this information based on **interventional treatment (TRE) trials** and **accruals** as reported by your cancer center on your most recent NCI Data Table 4. More information about interventional TRE trials as defined by the NCI and can be found on pages 21-23 of the [CCSG Electronic Data Guide](#) and also in the survey [data dictionary](#).

The CRI Steering Committee is recommending all AACI cancer center members participate in this survey so that they can be provided with information to benchmark themselves. Only centers who participate in the survey will be provided an aggregated summary survey report. The report will not contain individual cancer center information.

All questions about the survey may be emailed to C.J. Confair, [cj@aacI-cancer.org](mailto:cj@aacI-cancer.org). Thank you for participating in the survey. Please complete the survey by Friday, May 25.

1. Please enter your contact information so we may contact you for any questions.

Name

Title

Cancer Center Name

Email

2. Please indicate the start date and end date for the 12-month period you are using for reporting survey data. Data should not be older than 2016 and the same 12-month period should be used to answer all

questions.

Start Date (MM/DD/YY)

End Date (MM/DD/YY)

3. What is the **total annual budget in dollars** for the Clinical Trials Office for the indicated 12-month period you reported in Question 2? This should include support for the cancer center's clinical research operations and protocol review and monitoring and data safety monitoring committee activities. Please enter whole numbers only and no ranges. Data will only be presented in aggregate; your center's specific budget will not be shared.

4. Please indicate the **annual budget in dollars** for the CTO provided from each of the following sources of support. Please enter numbers only and no ranges. Data will only be presented in aggregate; your center's specific budget will not be shared.

	Budget in Dollars
<b>Institutional</b> - school of medicine, central university, health system, IIT support, philanthropic, state appropriated funds	<input type="text"/>
<b>Industry</b> - pharma or biotech	<input type="text"/>
<b>External</b> - NIH Grants, U01, R01, Spores, U10, PO1, CTEP	<input type="text"/>
<b>National Cooperative Group</b> - NCI NCTN, NCORP, etc.	<input type="text"/>
<b>Cancer Center Support Grant (CCSG)</b>	<input type="text"/>

5. Please indicate the **percentage of the institutional budget** that comes from the following categories. Please enter numbers as a percentage and no ranges. All four boxes should add up to 100%.

	Percent of Total Institutional Support
<b>State appropriated funds</b> - funds distributed by the state to the health system then allocated to the cancer center	<input type="text"/>
<b>IIT support</b>	<input type="text"/>
<b>Central university funds or medical center</b>	<input type="text"/>
<b>Philanthropy</b>	<input type="text"/>

6. Please indicate the **total number of analytical cases** as reported by your tumor registry department for the main cancer center and all other sites for the 12-month period indicated in Question 2.

**Main Cancer Center:** Tertiary care center also known as the flagship treatment and research facility (in and out patient) where state-of-the-art clinical services of the cancer center are provided.

**All Other Sites:** Include all trials that you have a role in conducting, e.g., trial activation or conduct of the trial at all sites other than the main cancer center. Your specific role in trial does not matter. This includes all sites outside of the main cancer center, where cancer care including clinical research treatments are provided regardless of the type of agreement or lack of agreement in place between the cancer center and networks, community hospitals, affiliates, physician practice sites, etc.

	Main Cancer Center	All Other Sites
<b>Analytical cases</b> - reported by your tumor registry	<input type="text"/>	<input type="text"/>

7. Please indicate the total number of **active interventional therapeutic (TRE) treatment clinical trials** by sponsor type for the same 12-month period. Please enter numbers only and no ranges.

Please do not include prevention, health science research, basic science, screening, supportive care, diagnostic, observational or any other trial types. The following definitions are provided to assist you with the survey questions:

**Active:** A protocol which has been IRB approved, may be open to accrual, closed to accrual or suspended, but is not closed by the IRB or trial sponsor. The trial must be active at some time in the 12-month period reported in Question 2.

**Interventional:** Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed. Interventions can also include noninvasive approaches, such as education or modifying diet and exercise.

**Treatment (TRE):** We are seeking trials coded on your NCI Data Table 4 with the primary purpose of Treatment (TRE). These are defined as trials designed to evaluate one or more interventions for treating a disease, syndrome, or condition. Note: This equates to therapeutic trials in previous versions of the NCI DT guidelines.

**Main Cancer Center:** Tertiary care center also known as the flagship treatment and research facility (in and out patient) where state-of-the-art clinical services of the cancer center are provided.

**All Other Sites:** Include all trials that you have a role in conducting, e.g., trial activation or conduct of the trial at all sites other than the main cancer center. Your specific role in trial does not matter. This includes all sites outside of the main cancer center, where cancer care including clinical research treatments are

provided regardless of the type of agreement or lack of agreement in place between the cancer center and networks, community hospitals, affiliates, physician practice sites, etc.

	Trials <u>only open</u> at the Main Cancer Center	Trials open at the Main Cancer Center and at least 1 other site
<p><b>National</b> NCI NCTN and other NCI/NIH-supported National Trial Networks</p>	<input type="text"/>	<input type="text"/>
<p><b>Industry</b> A pharmaceutical company controls the design and implementation of these clinical research studies.</p>	<input type="text"/>	<input type="text"/>
<p><b>Externally peer-reviewed</b> A clinical research study supported by the NIH or by organizations with peer review a funding system, (e.g., R01s, SP0RES, U01s, U10s, P01s, CTEP, etc.).</p>	<input type="text"/>	<input type="text"/>
<p><b>Institutional</b> In-house clinical research studies authored or co-authored by Cancer Center investigators and undergoing scientific peer review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing, and implementing the clinical research study and reporting results. It is acceptable for industry and other entities to provide support (e.g., drug, device, other funding), but the trial should clearly be the intellectual product of the center investigator. This category may also include an institutional trial authored and implemented by and investigators at your cancer center or another center in which your center is participating. This category can include multi-Institutional studies authored and implemented by investigators at your center or another cancer center.</p>	<input type="text"/>	<input type="text"/>

8. Please indicate the total number of **interventional therapeutic treatment clinical trial accruals** for each category representing sponsor type for the same 12-month period. Please enter numbers only.

Please do not include prevention, health science research, basic science, screening, supportive care, diagnostic, observational or any other types.

**Accrual:** The total number of participants registered/enrolled on to a study and will either complete the study or in the process of completing the study.

**Main Cancer Center:** Tertiary care center also known as the flagship treatment and research facility (in and out patient) where state-of-the-art clinical services of the cancer center are provided.

**All Other Sites:** Include all trials that you have a role in conducting, e.g., trial activation or conduct of the trial at all sites other than the main cancer center. Your specific role in trial does not matter. This includes

all sites outside of the main cancer center, where cancer care including clinical research treatments are provided regardless of the type of agreement or lack of agreement in place between the cancer center and networks, community hospitals, affiliates, physician practice sites, etc.

	Main Cancer Center Accruals	All Other Sites Accruals
<b>National</b> NCI NCTN and other NCI/NIH-supported National Trial Networks	<input type="text"/>	<input type="text"/>
<b>Industry</b> A pharmaceutical company controls the design and implementation of these clinical research studies.	<input type="text"/>	<input type="text"/>
<b>Externally peer-reviewed</b> A clinical research study supported by the NIH or by organizations with peer review a funding system, (e.g., R01s, SP0RES, U01s, U10s, P01s, CTEP, etc.).	<input type="text"/>	<input type="text"/>
<b>Institutional</b> In-house clinical research studies authored or co-authored by Cancer Center investigators and undergoing scientific peer review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing, and implementing the clinical research study and reporting results. It is acceptable for industry and other entities to provide support (e.g., drug, device, other funding), but the trial should clearly be the intellectual product of the center investigator. This category may also include an institutional trial authored and implemented by and investigators at your cancer center or another center in which your center is participating. This category can include multi-Institutional studies authored and implemented by investigators at your center or another cancer center.	<input type="text"/>	<input type="text"/>

9. For **interventional therapeutic treatment clinical trials**, please indicate the median time (calendar days, including weekends) for each step below for all trial sponsors.

Please do not include prevention, health science research, basic science, screening, supportive care, diagnostic, observational or any other types. Please enter numbers only and no ranges.

	Calendar days
From receipt of the protocol to SRC/PRC approval	<input type="text"/>
From SRC/PRC approval to IRB approval	<input type="text"/>
From full IRB approval to study activation date (when consent to enroll subjects is released)	<input type="text"/>
From contract draft receipt to institution's contract/legal department to execution	<input type="text"/>
From SRC/PRC approval to first patient accrued	<input type="text"/>
From initial trial budget review to trial budget approval by the sponsor.	<input type="text"/>



10. Please indicate the number of staff on-boarded, including recruitments, contracted, temporary, or permanent staff, within the CTO to support **interventional therapeutic treatment** (TRE) clinical trials for the same 12 month period reported in Question #2.

The dates listed below are what you entered in Question #2 as the start and end of your 12-month period for reporting. You do not need to fill in the text boxes beside the dates.

Number of staff on-boarded

» Start Date (MM/DD/YY)

» End Date (MM/DD/YY)

11. As of today, please indicate the number of full time equivalents (FTEs), including approved vacancies, (e.g., 1.0 FTE = 40 hours; 0.5 FTE = 20 hours) working with **interventional therapeutic treatment clinical trials** for the following roles and indicate if they are covered by the CTO budget. Please only count each person once. If you need help defining any of these positions, please use the survey glossary.

Example: If data management is done by dedicated team of data managers, please provide the number of FTEs for this activity. If you do not have a dedicated data managers and this task is completed by a trial coordinators, please do not include numbers for this activity in the data management field.

	Number of FTEs	Position covered by CTO budget	Number currently vacant
	Number of FTEs	Position covered by CTO budget	Number currently vacant
CTO medical director	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
CTO administrative director	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
Administrative support (administrative assistant)	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
CTO management (supervisor of clinical research staff, program manager)	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
PRMC and ancillary committee administration	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
Clinical research coordination - (RN nurse role)	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
Clinical research coordination - (non-RN nurse)	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
Statistical analysis (statistician)	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
Contracts/budgeting/cost recovery	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
Dedicated Trial coverage analysis/billing compliance	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
Research pharmacy	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>
Dedicated Quality assurance/audit	<input style="width: 80px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input style="width: 80px; height: 20px;" type="text"/>

	Number of FTEs	Position covered by CTO budget	Number currently vacant
	Number of FTEs	Position covered by CTO budget	Number currently vacant
Dedicated regulatory management staff and not done by a coordinator	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Dedicated training/education staff	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Dedicated research specimen collection staff and not done by a research coordinator	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Dedicated medical ethics role	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Clinical trials management application (CTMA) analyst/ Programmer	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Data safety monitoring committee (DSMC) administration	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Data management (if not done by a coordinator)	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Dedicated site visit coordination (if not done by a coordinator position above)	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Dedicated Trial implementation (if not done by a position above)	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Navigator or patient advocate	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Other, please specify: <input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Other, please specify: <input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
Other, please specify: <input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<b>Comments</b>			
<input type="text"/>			
<p>You have reached the end of the survey, please review your answers before submitting the survey. Once you submit the survey, you will not be able to make any edits. If you have any questions please contact C.J. Confair, <a href="mailto:cj@aaci-cancer.org">cj@aaci-cancer.org</a>.</p> <p>Are you sure you want to submit the final survey? If yes, please submit the survey by clicking the arrow below.</p> <p><input type="checkbox"/> Yes</p>			

## APPENDIX B: GLOSSARY

### NCI Definitions – Data Table 4 Full information packet

- **Reporting Start Date** – The date on which the center-defined 12-month reporting period started
- **Reporting End Date** – The date on which the center-defined 12-month reporting period ended
- **Clinical Research Cat** – The Clinical Research Category in which the clinical research or protocol is listed valid entry: INT, OBS, or ANC/COR. **For this survey we only want INT.**
- **Study Source** – The category of the trial sponsor or study source: National Cooperative group, Externally peer-reviewed, Institutional, Industry.
- **Primary Purpose** – The type or primary purpose of clinical trial. Primary purpose the trial, as follows: Tre: Treatment, Pre: Prevention, Sup: Supportive Care, Scr: Screening, Dia: Diagnostic, Hsr: Health Services Research, Bas: Basic Science, Dev: Device Feasibility, Oth: Other, Valid entry: Tre, Pre, Sup, Scr, Dia, Hsr, Bas, Dev, or Oth. **For this survey we only want Tre.**

### Survey Specific Definitions

**Main Cancer Center.** Tertiary care center also known as the flagship treatment and research facility (in and out patient) where state-of-the-art clinical services of the cancer center are provided.

**All Other Sites.** Include all trials that you have a role in conducting, eg, trial activation or conduct of the trial at all sites other than the main cancer center. Your specific role in trial does not matter. This includes all sites outside of the main cancer center, where cancer care including clinical research treatments are provided regardless of the type of agreement or lack of agreement in place between the cancer center and networks, community hospitals, affiliates, physician practice sites, etc.

**Active Trial.** A protocol which has been IRB approved, may be open to accrual, closed to accrual or suspended, but is not closed by the IRB or trial sponsor. The trial must be active at some time in the 12-month period reported.

**Accrual** – The total number of participants registered/enrolled in a study and will either complete the study or are in the process of completing the study.

**Interventional** – Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed. Interventions can also include non-invasive approaches, such as education or modifying diet and exercise.

**Treatment (TRE)** – We are seeking trials coded on your NCI Data Table 4 with the primary purpose of Treatment (TRE). These are defined as trials designed to evaluate one or more interventions for treating a disease, syndrome, or condition. Note: This equates to therapeutic trials in previous versions of the NCI DT guidelines. National Cooperative Group.

NCI NCTN and other NIH-supported National Trial Networks/Industry.

A pharmaceutical company controls the design and implementation of these clinical research studies. Externally Peer-Reviewed.

A clinical research study supported by the NIH or by organizations with peer review a funding system, (eg, R01s, SP0RES, U01s, U10s, P01s, CTEP, etc.). Institutional.

In-house clinical research studies authored or coauthored by Cancer Center investigators and undergoing scientific peer review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing, and implementing the clinical research study and

reporting results. It is acceptable for industry and other entities to provide support (eg, drug, device, other funding), but the trial should clearly be the intellectual product of the center investigator. This category may also include an institutional trial authored and implemented by and investigators at your cancer center or another center in which your center is participating. This category can include multi-Institutional studies authored and implemented by investigators at your center or another cancer center.

### Definitions of Clinical Trials Office (CTO) or Clinical Research Staff Positions:

**CTO medical director** – a physician director providing oversight of the medical conduct of the trials included in the cancer center's clinical research program, may provide investigator education, address noncompliance with investigators, participate in the data safety monitoring committee (DSMC) activities, etc.

**CTO administrative director** – leads the cancer center's clinical trials office operations regardless of whether the office is centralized or decentralized.

**Administrative support** (administrative assistant) – provides administrative support to the CTO medical director, CTO administrative director or other CTO manager or program managers.

**CTO management** (supervisor of clinical research staff, program manager) – provides oversight of nurse and/or nonnurse coordinators, regulatory staff, data managers, QA/Audit staff, community research staff, etc.

**PRMC and ancillary committee administration** – coordinate the activities of the cancer center's protocol review and monitoring activities to include scientific review and/or data safety monitoring.

**Clinical research coordination** – RN nurse role who may do some of these responsibilities and work under the CTO administrative director, medical director and PI or coinvestigator. Screen and enroll patients to clinical trials, coordinate patient care, educate study subjects and clinical staff about the trial, collect research data, administer study agents, report adverse events, supervise other research staff, study coordinators and data managers.

**Clinical research coordination** – non-RN nurse who may do some of these responsibilities and work under the CTO administrative director, medical director and PI or coinvestigator. Screen and enroll patients to clinical trials, coordinate patient care, educate study subjects and clinical staff about the trial, collect research data, administer study agents, report adverse events, supervise other research staff, study coordinators and data managers.

**Statistical Analysis** – use of a statistician who creates the statistical section of protocol that is agreement with the aims of the trial and/or provides statistical analysis of the trial data as per the trial's objectives.

**Contracts/budgeting/cost recovery** – one or more staff who are responsible for creating the trial budget expense related to conducting the trial, responsible for negotiating the terms of the trial contract with the sponsor, and who may invoice the sponsor for trials services provided as per the terms of the contract or agreement.

**Dedicated Trial coverage analysis/billing compliance** – one or more staff who review the protocol to develop a local coverage determination to ensure provider compliance per 3<sup>rd</sup> party payer regulations.

**Research pharmacy** – responsible for accepting, storing, inventorying and dispensing trial agents as per the protocol.

**Dedicated Quality assurance/audit** – responsible for reviewing the trial's regulatory document and/or research data for trial compliance.

**Dedicated regulatory management staff and not done by a coordinator** – responsible for the creation and management of research regulatory documents required for the approval and conduct of a trial, coordinate IRB approval, create and submit the trial IND to the FDA, and create and maintain other required sponsor documentation.

**Dedicated training/education staff** – responsible for providing research training to new or existing staff, investigators, and clinical staff.

**Dedicated research specimen collection staff and not done by a research coordinator** – responsible for collecting and/or processing and shipping research blood and tissue specimens.

**Clinical trials management application (CTMA) analyst/ Programmer Data safety monitoring committee (DSMC) administration** – responsible for managing the institution's home grown or commercial CTMA. May create cancer center trial reports, dashboards to be used by leadership or act as an interface between the cancer center and the commercial vendor or technology department.

**Data Management** – Staff who abstracts data from the patients' medical records and enters on to paper or electronic case report forms (CRF) or clinical trial management application. These staff may address data queries.

**Dedicated site visit coordination** (if not done by a coordinator position above) – staff responsible for scheduling and coordinating sponsor site visits. May facilitate follow-up correspondence to sponsor site visit reports.

**Dedicated Trial implementation** (if not done by a position above) – responsible for assisting the investigators and CTO staff in preparing the trial for review by cancer regulatory review committees, SRC or feasibility, assist with sponsor site qualification visits or implementation visits with the sponsor or cancer center to activate the trial.

**Navigator or patient advocate** – Nurse or nonnurse who screen patients for trials, may work with a specific patient population to transition on or off a clinical trial, address financial issues not covered by payers, etc., help with educating patients about trials, address patient concerns about going on a trial, serve on cancer trial committees.

## APPENDIX C: SURVEY RESPONDENTS

Abramson Cancer Center of the University of Pennsylvania

Albert Einstein Cancer Center

Barbara Ann Karmanos Cancer Institute

BC Cancer

Boston University Cancer Center

Cardinal Bernardin Cancer Center

Case Comprehensive Cancer Center

City of Hope Comprehensive Cancer Center

Cleveland Clinic Taussig Cancer Institute

Dan L Duncan Comprehensive Cancer Center

Dana-Farber Cancer Institute

Dartmouth-Hitchcock Norris Cotton Cancer Center

Duke Cancer Institute

Fox Chase Cancer Center, Temple Health

Fred Hutchinson Cancer Research Center

Georgetown Lombardi Comprehensive Cancer Center

Herbert Irving Comprehensive Cancer Center

Holden Comprehensive Cancer Center

Hollings Cancer Center

Huntsman Cancer Institute

Indiana University Melvin & Bren Simon Cancer Center

Knight Cancer Institute

Laura and Isaac Perlmutter Cancer Center at New York University Langone

Loma Linda University Cancer Center

Masonic Cancer Center

Mayo Clinic Cancer Center

Mays Cancer Center

Medical College of Wisconsin Cancer Center

Memorial Sloan Kettering Cancer Center

Moffitt Cancer Center

Penn State Cancer Institute

Princess Margaret Cancer Centre

Roswell Park Comprehensive Cancer Center

Rutgers Cancer Institute of New Jersey

Samuel Oschin Comprehensive Cancer Institute

Sidney Kimmel Cancer Center at Thomas Jefferson University

Sidney Kimmel Comprehensive Cancer Center

Simmons Comprehensive Cancer Center, University of Texas Southwestern Medical Center

Siteman Cancer Center

Stanford Cancer Institute

Stephenson Cancer Center

Sylvester Comprehensive Cancer Center

The Ohio State University Comprehensive Cancer Center James Cancer Hospital & Solove Research Institute

The Robert H. Lurie Comprehensive Cancer Center

The Tisch Cancer Institute at the Mount Sinai Health System

The University of Chicago Medicine Comprehensive Cancer Center

The University of Kansas Cancer Center

The University of Vermont Cancer Center

University of Arkansas for Medical Sciences Winthrop P. Rockefeller Cancer Institute

University of California (UC) Davis Comprehensive Cancer Center

UC San Diego Moores Cancer Center

UCI Chao Family Comprehensive Cancer Center

UC, Los Angeles, Jonsson Comprehensive Cancer Center

UC, San Francisco, Helen Diller Family Comprehensive Cancer Center

University of Kentucky Markey Cancer Center

University of North Carolina at Chapel Hill Lineberger Comprehensive Cancer Center

University of Cincinnati Cancer Institute

University of Colorado Cancer Center

University of Florida Health Cancer Center

University of Hawaii Cancer Center

University of Illinois Cancer Center

University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center

University of Michigan Rogel Cancer Center

University of New Mexico Comprehensive Cancer Center

University of Texas MD Anderson Cancer Center

University of Texas Medical Branch Cancer Center

University of Virginia Cancer Center

University of Wisconsin Carbone Cancer Center

University of Louisville Brown Cancer Center

University of Pittsburgh Medical Center Hillman Cancer Center

Upstate Cancer Center

University of Southern California Norris Comprehensive Cancer Center

Vanderbilt-Ingram Cancer Center

Virginia Commonwealth University Massey Cancer Center

Wake Forest Baptist Comprehensive Cancer Center

Wilmot Cancer Institute

Winship Cancer Institute

West Virginia University Cancer Institute

Yale Cancer Center