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Commentary

Defining the Role of the CTO Medical Director at AACI Cancer Centers

By CTO Medical Directors' Forum Co-chairs

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Commentary Overview

- AACI's Clinical Research Innovation (CRI) recently established a dedicated listserv for medical directors at clinical trials offices (CTO) and a CTO Medical Directors' Forum.
- The forum has taken steps to standardize the CTO medical director position across AACI's cancer center network.
- During a virtual roundtable earlier this month, participants discussed the results of a survey distributed to CTO medical directors to begin defining the role and identifying mentorship opportunities.

A key component of AACI's mission is to advance the objectives of its 102 member cancer centers by facilitating interactions and developing best practices. AACI's Clinical Research Innovation (CRI) provides a network for cancer center clinical research leaders to collaboratively address clinical research challenges through listserv discussions, working groups, and annual meetings.

CRI recently established a private listserv for medical directors at clinical trials offices (CTO) and a CTO Medical Directors' Forum to provide peer-to-peer networking and knowledge-sharing opportunities for CTO medical directors.

Recognizing that this role lacks consistency across AACI's cancer center network, the forum has taken initial steps to develop standards for the position.

In May 2020, AACI distributed a survey to CTO medical directors to gather information about the duties they perform at their individual centers and the ways that AACI cancer centers provide oversight of clinical research programs.

The survey was sent to 86 CTO medical directors with 57 respondents fully completing the survey.

On November 10, the forum hosted a virtual roundtable discussion during which the survey data were summarized and participants began developing a framework of responsibilities for CTO medical directors.

Based on the survey data, we learned that more than half of respondents either do not have a formal job description or defined criteria at their cancer center for selecting CTO medical directors. In addition, most do not receive performance feedback. Individuals with CTO medical director responsibilities hold a variety of titles at their cancer centers. Organizational structures also vary widely, with CTO medical directors reporting to the associate director for translational and clinical research, executive vice president of research, senior director of clinical research, chief scientific officer, or cancer center director, among others.

Along with comprehensive medical knowledge, the ability to balance multiple interests was cited as a key attribute of CTO medical directors. Respondents reported that their primary role is as a liaison connecting clinical investigators, community physicians, and clinical trials office staff at the cancer centers to offer clinical trials within their catchment areas and to foster communication.

Other important tasks of the CTO medical director include clinical research advocacy, aligning clinical research goals with the goals of the cancer center as a whole, providing long-term strategic plans, clinical operations, billing, and voicing the needs of the CTO to the larger institution.

In spite of this wide range of responsibilities, 67 percent of respondents stated that their decision-making capacity is limited, with an additional 4 percent reporting that they have no authority to make decisions for their CTO. One respondent noted that this is a result of poorly-defined boundaries between the CTO medical director and other positions, particularly the associate director for clinical research.

A few centers noted that the CTO medical director and the associate director for clinical research are the same person at their institution and asserted that this allows for more protected time, with the dual role providing leverage for the CTO to access resources and support. However, most institutions have a distinct CTO medical director. The survey determined that average protected time was around 23 percent, though most medical directors reported actual time devoted to clinical trial director duties exceeded allotted protected time.

Roundtable participants described the role of CTO medical directors at their centers, and agreed to a goal of developing guidance for centers on necessary qualifications for the CTO medical director position, defining the role and responsibilities more clearly, and recommending how the CTO medical director works within the center. They also reviewed the ideal length of service in this role and how to develop succession planning.

As noted in the **December 2019 AACI *Commentary***, industry partners consistently communicate that individual cancer center CTOs are the "most expensive" and the "slowest" when compared to their peers. In order to improve trial activation and efficiency, CTOs must leverage their collective value and work to improve collaboration with industry partners. Several medical directors are part of a newly launched working group with AACI Corporate Roundtable partners to improve trial activation timelines.

Moving forward, the CTO Medical Directors' Forum will host quarterly virtual roundtable meetings to provide a platform for CTO medical directors to share best practices, discuss ongoing challenges, and—most importantly—mentor new directors. They will also continue to utilize the newly developed CTO medical director listserv to discuss real-time questions and best practices. The CTO Medical Directors' Forum is a wonderful mechanism to bring together this group of physician leaders and offer them a close-knit community for clinical trials discussions.

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