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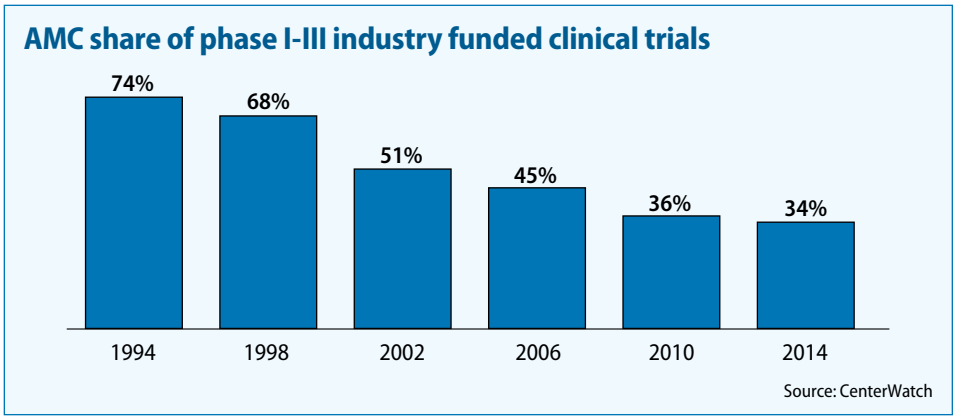
Growing role for AMC clinical trial offices

CTOs gaining leverage; expanding capabilities; improving performance

By Lisa Chontos

As federal funding for clinical research continues to decrease, academic medical centers (AMCs) are strengthening clinical trial offices (CTOs) on their campuses.

Though challenges run the gamut of turnaround time, stretched resources and faculty issues, rising benefits such as improved start-up times, new funding and expanding service offerings show that CTOs are gaining visibility and leverage within AMCs.



Challenges of CTOs in AMCs

The use of CTOs in AMCs may offer significant value to industry sponsors, but they are not without their difficulties, some of which have persisted over the years.

When conducting clinical trials in AMCs, a long-standing drawback is turnaround time, which is due to multiple hand-offs between the sponsor, principal investigator, IRB and CTOs.

Dr. Ravi Thadhani, executive director of the CTO at Massachusetts General Hospital, said, "AMCs have developed the unfortunate reputation of being slow to begin new clinical trials, often because of complex contracting and initiating processes. The contracting and budgetary expertise of a CTO can mitigate these delays by assisting those investigators who may not have experience in these areas."

CTOs have been found to lack resources in areas ranging from staffing to software. Kimberly Irvine, executive vice president and COO of the Biomedical Research Alliance of New York (BRANY), noted, "Staffing may not be sufficient to support the size of the program, or technology such as a clinical trial management system may not be suitable or may not be in place at all."

Faculty's perception of the support provided can also affect how smoothly the CTO runs. A lack of commitment can cause the system to break down. If some investigators fail to see the value of the CTO, they might limit their contact with the CTO and its infrastructure. The result is a mixed approach within a site, with certain investigators preferring to have industry contact them directly for trials and others preferring to receive trials through the trial office.

"In these situations, industry wants to support the use of the CTO but is balancing that against maintaining relationships with physicians they have worked with directly for quite some time," said Tracey Gashi, senior director of Site and Patient Access at INC Research.

On the other hand, some faculty may feel insufficiently supported and contemplate the need for more individual assistance with their particular programs or research efforts. "In some cases, faculty may voice concerns regarding prioritization amongst an array of research endeavors," said Jean Gatewood, former director of the Office of Clinical Trials at New York University Medical Center, with extensive experience in both industry and at an AMC.

From the industry side, a source of frustration has also been the fact that the relationship being built remains within the CTO, rather than directly reaching the investigators conducting the trials.

Recent improvements

CTOs have made marked progress in recent years. One improvement is the introduction of metrics, along with implementing systems that report those metrics and

CTO characteristics

Mean number of years supporting clinical trial activity	22
Mean number of investigators served	31
Mean number of full-time administrative staff	3
Average percentage of funding coming from industry	65%

Source: CenterWatch, 2015; n=64 AMCs

support decision making. Gatewood said, "These data clearly indicate efficiencies and effective processes—or highlight opportunities for change—so a sponsor can confidently move in lock-step with sites through selection, startup and study conduct."

Irvine of BRANY pointed out that multiple factors affect startup. "When we have buy-in from the investigator and the study sponsor, we have seen studies get through the study startup process in as little as 38 days, including budget and contract negotiations and IRB review. For a PI at an AMC to get a study ready for activation that quickly is excellent."

She said, "We have also seen startup halted significantly when sponsors are waiting for protocol amendments to be produced or they are awaiting responses from the FDA. Oncology studies in particular can also be impacted by various levels of review, such as scientific review by the department, radiation safety and IRB review—each of which impacts the timelines."

In the U.S., CTOs have started to become a one-stop shop for both their internal research communities and industry sponsors. CTOs help sponsors identify potential internal investigators for trials, and the relationships CTOs develop with industry sponsors provide the AMCs with information on upcoming trials.

"The recent trend toward tertiary referral patterns to AMCs provide sponsors with access to rare and/or complex disease state patient populations not available in community healthcare settings," said Thadhani of Massachusetts General Hospital.

The Implementation of new software is also increasing efficiency. Many AMCs have begun using clinical trial management systems (CTMS) to help investigators coordinate their trials.

At the Partners Healthcare Clinical Research Office, founded by Brigham and Women's Hospital and Massachusetts General Hospital, a CTMS will be rolled out over the next three months. BRANY uses a CTMS called SMART—Study Management and Revenue Tracking System. Although it was built in collaboration with a software developer, it is also commercially available.

Irvine said, "I think a lot can be done in the area of study feasibility and patient identification in research through the EMR systems, and I believe organizations are having success in this area. There are many tools, like Exploris and Clinical Looking Glass, that are available to researchers at different institutions. I can see CTOs providing support to researchers in running queries based on inclusion/exclusion, etc., through these systems."

New funding alternatives

Alternative operating and funding models are now often sought for CTOs. "Some AMCs use cost share for IDC and a federated operating model," Erika Stevens, senior managing director of FTI Consulting, who formerly ran two clinical trial offices and currently assists CTO clients with operational improvement, said.

Other options will soon be available, as well. NYU Medical Center's Gatewood is

currently developing another alternative. "I have introduced the concept of hybrid modeling," she explained, "to support the complex and varied needs of institutions in their pursuit of scientific knowledge and treatment options."

At the same time, CTOs are motivated to maintain their ties with industry to benefit from the funding that comes with a greater volume of commercial clinical trials. The increased revenue from commercial clinical work can be used to justify office staffing and persuade investigators of the value of the office.

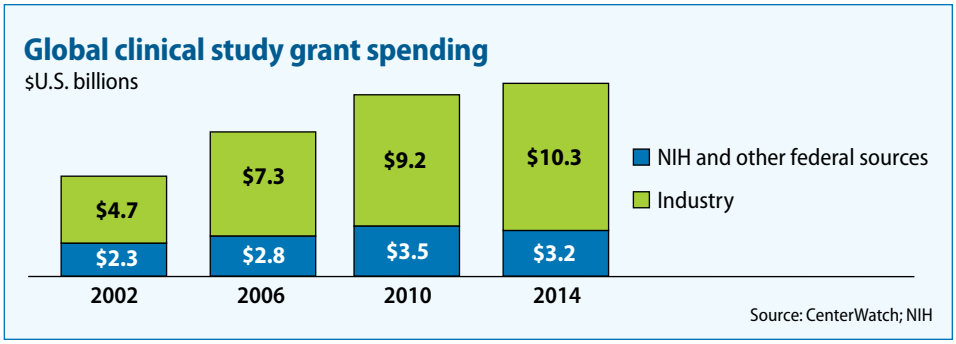
Additional service changes on the horizon

CTOs in AMCs are also expanding their services. Industry experts see room for improvement in many areas, from how services are presented and delivered to how study subjects are recruited.

Gashi at INC Research proposed that harmonizing the services offered would enable industry to quickly understand the standard set of services offered. Furthermore, she observed that CTOs that provide a one-stop shop and coordinate all aspects of the clinical trial from startup through study execution are more attractive than those that only provide a centralized administrative function.

Likewise, a basic element determining how smoothly trials run is the investigators' acceptance of the CTO infrastructure. "Clinical trial offices should also ensure that the value they offer is clearly communicated and understood by all internal stakeholders, particularly with [regard to] investigators," Gashi said. "Gaining buy-in from investigators would avoid the mixed model we often see today."

While processes are completed more quickly than in the past, even faster turnaround is essential. Thadhani said, "The nature of private industry requires them to bring services and products to market as quickly as possible. This translates into the need to start up and conduct trials as quickly as possible. As expenses for trials continue to climb, industry sponsors will require CTOs to expedite contracting, budgeting and site startup."



Patient participation and subject selection could be improved if aggregate center and catchment area data were carefully, collaboratively shared, noted Gatewood.

Gatewood also sees a significant opportunity to bring more relevant studies and subjects together by harnessing sponsors' robust marketing power and technology. "By offering such support to sites and deploying these capabilities from the outset for the duration of study conduct, sponsors will be effectively powering the success of the studies they've made incredible monetary investments in," she explained.

As technology in healthcare continues to grow, experts anticipate more collaboration between technology transfer offices and CTOs, especially in the device industry. Thadhani said that at Massachusetts General Hospital, "We are receiving inquiries from designers and manufacturers to conduct trials using mobile applications in both inpatient and outpatient settings."

The future of CTOs in AMCs

Overall, funding of clinical trials continues to shift from federal sources to industry sponsors, and CTOs will be forced to evolve, becoming increasingly responsive and forward-thinking to stay in step with industry needs.

In the future, CTOs must continue to expand the variety of services they offer. As institutions move toward working with numerous IRBs, CTOs are stepping in to coordinate those efforts and ensure compliance with AMC policies and procedures.

Relationships between CTOs and sponsors should also be strengthened, directly benefiting the collaboration. "Developing 'preferred provider' relationships with industry partners across a variety of clinical specialties positions a CTO as a first-choice collaborator when sponsors are selecting sites for new trials," said Thadhani.

Gatewood sees a need for sites and sponsors to collaborate on expense reconciliation as well as auditing processes and personnel, in addition to the conduct and data. Such a collaboration would bring in more high-powered professionals to support clinical protocol and data management and ultimately move novel indications through the approval process and to market.

"Until true partnership exists, clinical care will advance, but not at the pace healthcare consumers need it to," said Gatewood. "I can say, firsthand, there are plenty of visionary people thinking and talking strategically. … However, we do need to cultivate more of this innovative collaborative approach to the clinical research effort."

Lisa Chontos is a freelance medical writer with 15 years of experience writing for hospitals, biotech firms, pharmaceuticals companies and publications like CenterWatch. Email lisa@lisachontos.com.