Cancer Clinical Trials & Affiliation Evaluation

6 critical dimensions to assess during any affiliation evaluation process

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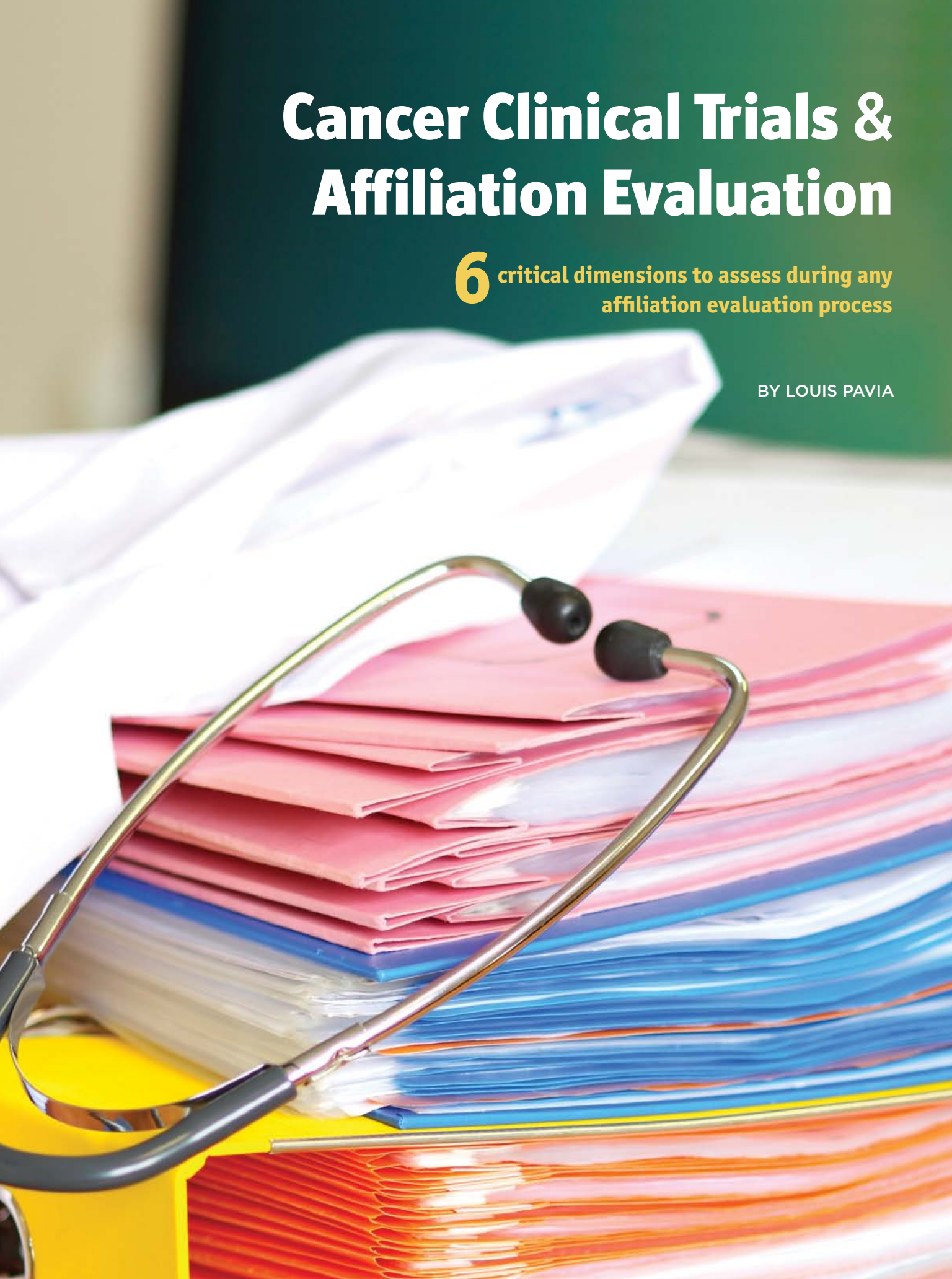

Oncology services are experiencing a wave of consolidation. While financial pressures are often the primary factor driving consolidation, improving patient care quality should be key criteria for evaluating potential affiliation partners. The Institute of Medicine (IOM)[1], the National Comprehensive Cancer Network[2], and leading cancer care providers agree, the best care for a patient diagnosed with cancer is on a clinical trial. Integrating research into routine cancer care at the community level is vital to expanding access to quality care for patients close to home and necessary for community oncologists to deliver high quality care and attract and retain patients. Cancer clinical trials (CCTs), when executed effectively, can also be instrumental in physician alignment, clinical integration, and market share development.

The Changing Landscape

An annual survey of oncology practices found that over the past 4.5 years 241 oncology clinics have closed, 392 oncology practices have entered into purchase or management services agreements with hospitals, and 132 practices have merged or been acquired.[3] Some oncology practices are consolidating back office functions or entering into services agreements with hospitals or management companies to gain economies of scale and improve infrastructure (e.g., Carolinas Cancer Care with Carolinas HealthCare System). Others are merging to offer coordinated care on a regional or statewide basis (e.g., Regional Cancer Care Associates, Tennessee Oncology with Chattanooga Oncology and Hematology Associates).

Consolidation is also affecting hospital-based providers. Hospitals are merging and consolidating their cancer programs to increase patient volumes and improve efficiency (e.g., University of California San Diego Health System and Nevada Cancer Institute; Temple University Health System and Fox Chase Cancer Center; University of Rochester and Pluta Cancer Center; Kansas University Cancer Center and the Kansas City Cancer Center).

Community cancer centers are networking with NCI-designated cancer centers and academic medical centers to expand the scope and quality of care they offer (e.g., The University of Arizona Cancer Center and St. Joseph's Hospital and Medical Center; UCSF Helen Diller Family Comprehensive Cancer Center and Community Hospital of the Monterey Peninsula; Duke Medicine and Augusta Health Cancer Center).

To manage cancer care and share financial risks and rewards, health systems, payers, and oncology practices are forming cancer accountable care organizations (ACOs) (e.g., Baptist Health South Florida/Florida Blue/American Medical Specialties) and medical homes (Space Coast Cancer Center).

The State of Clinical Trials Today

Patients understand the value of research and are willing to participate in CCTs but often lack the information and support to do so. Seventy-six percent of Americans believe clinical trials are of great value and another 22 percent believe they are of some value.[4] The Mayo Clinic found that 76 percent of patients expected their doctor to inform them about clinical trials, but only 58 percent were satisfied with their current knowledge of CCTs.[5] Patients trust their doctor most for health information, but only 10 to 20 percent of patients with cancer are informed about clinical trials by their oncologist.[6]

While community oncologists are integral to the CCT process, they must have the knowledge, tools, and inclination to educate patients about CCTs as a treatment option when available. One study of nearly 500 medical oncologists found that 60 percent referred or enrolled one or fewer patients per month to a clinical trial.[7] For other cancer specialties, nearly 60 percent refer or enroll less than 1 per year.[7] Referring physicians can play an important role in educating patients diagnosed with cancer about clinical trials as a treatment option, but 98 percent of these referring physicians never discuss clinical trials with patients they refer to a cancer specialist.[8]

Perhaps the greatest barrier to accelerating improvements in cancer care is the failure of the clinical trial enterprise. Forty percent of NCI-supported trials do not achieve accrual goals and are not completed or published.[9] Among the Phase III trials, nearly 64 percent did not achieve accrual success, and about half of Phase III trials closed to accrual with enrollments less than 25 percent of the originally stated accrual goal.[9] (Some trials do close early because of unanticipated side effects or other clinical factors).[9] Stunningly, 38.8 percent of cooperative group trials and 20.6 percent of non-cooperative group trials failed to accrue a single patient.[10]

Clinical Trials: A Benefit of Affiliation

So what can be done to improve CCTs? One way to fully capitalize on the benefits of clinical trials may be through an affiliation that allows the cancer program to expand access to clinical trials and deliver quality patient care. While cancer clinical trials are frequently identified as a potential benefit of an affiliation, there is often too little due diligence on the means and capabilities of capitalizing on that opportunity. Following are six critical dimensions of CCTs that should be assessed as part of any affiliation evaluation process. They can also provide a framework to continually assess the value of the relationship.

1. Vision and culture
2. Trials portfolio
3. Trial initiation
4. Accrual
5. Outreach
6. Support.

Cancer care is becoming increasingly complex and, ideally, more personalized. The trend toward targeted therapy and personalized medicine—as well as the increasing availability of genomic analysis for relevant targeted therapies and clinical trials—requires the screening of large numbers of patients to find particular population subsets who may be interested in participating in these trials. Community oncologists who

participate in clinical trials not only extend quality care and trial access to the patients they serve, but also gain the experience and expertise they need to provide the resulting personalized care that is appropriate and expected by their patients.

1—Vision & Culture

Having a vision for cancer research that recognizes the role of clinical trials in quality patient care is paramount. Keep in mind, however, that the vision articulated in a statement may not be shared or reflected in the actual culture of the organization. In order to understand your potential partner's true vision and culture you should determine:

- What is the role of research in the mission and strategy of the organization?
- Is the stated vision understood and internalized throughout the organization (executives, managers, clinicians, and research staff) and reflected in actual behavior?
- How is the vision reflected in the budget and compensation scheme?
- Are their resources sufficient to achieve the vision?
- Are priorities consistent across departments and do they communicate and cooperate on research projects?
- Is research an expected part of quality patient care and reflected in performance measures?
- What is the strategy and capacity for handling biospecimens, new research plans, and future direction?

2—Trials Portfolio

Protocols are becoming increasingly complex and exclusion criteria more stringent. The appropriate mix of well-designed trials must be available if your patients and clinicians are to participate in the CCT process. This means assessing:

- Do the trials offered match the incidence of diseases and stages of your patient population?
- Is the mix of therapeutic and interventional studies by phase appropriate?
- Can your patient population qualify for the studies or will common co-morbidities or other factors typically exclude them?
- Can your clinicians and patients comply with the protocol requirements?
- Is there an appropriate mix of industry and grant-funded research?
- Is there an effective process for selecting trials to be offered?
- Are innovative trial design concepts (virtual, cluster randomization, adaptive design) being utilized?

3—Trial Initiation

There is a strong correlation between the time it takes to activate a trial and success in achieving accrual goals. Trials requiring less than 12 months of development are significantly more likely to achieve accrual goals.[8] You should determine:

- How long does it take, on average, for an investigator-initiated trial to be designed and approved?
- How long for an NCI Cooperative study to be approved?
- How long for an industry study to be approved?
- How long does the contracting process typically take?
- Are the appropriate patient protection protocols in place (IRB process)?
- Is the approval process efficient and effective?

4—Accrual

There are numerous barriers to participation in clinical trials from trial design, to timeliness, to patient resistance, to poor communications. But before patients can participate in a clinical trial they must first be offered the opportunity. The Education Network to Advance Cancer Clinical Trials (ENACCT) has identified several key goals and best practices for the CCT accrual process, including 100 percent of patients beginning cancer treatment to be effectively screened and 100 percent of eligible patients to be offered participation and provided the information they need to make an informed decision.[11] Tools and processes for screening patients, obtaining informed consent, and complying with the trial requirements are critical to effective accrual. When you look at the organization with which you are considering affiliating, first ask:

- What percent of trials achieve their accrual targets?
- What percent accrue 0 patients?
- How are open trials identified and accessed?
- How are they promoted?
- What percent of patients are (pre) screened?
- What screening tools (e.g., EMR, EHR, health information exchange) and techniques are used?
- Who is involved in screening (e.g., navigators, case managers, trial support staff)?
- Is there a systematic approach to screening patient charts for eligibility?
- Are all eligible patients actually approached?
- Are there culturally appropriate informed consent materials and processes?

5—Outreach

Patients need time to process their cancer diagnosis before they make decisions about treatment, but time is often of the essence. Less than 10 percent of newly-diagnosed cancer patients are informed about the possibility of participating in a cancer clinical trial by their physician.[12] Most patients are willing to participate in a CCT when asked; focus groups with the public and caregivers found that negative attitudes significantly changed after learning more about clinical trials.[6] ENACCT has demonstrated that training programs can increase knowledge and behavioral intent among community-based organizations *and* referring providers.[13] In order to ensure your community is aware of the potential benefits of CCTs, you should find out from your affiliating partner:

- What programs and materials are used to raise awareness in the patient community? Among oncologists? With primary care providers (PCPs) and other referring physicians (GI, OB/gyn, neuro, urology, breast surgeons)?

- What joint outreach initiatives will be undertaken?
- What role do community oncologists and referring physicians play in the care of patients on clinical trials?
- What outreach events are planned, when are they scheduled, and what is the CCT component?
- What is the social media plan for building CCT awareness?

6—Support

Cancer clinical trials are often complex and expensive undertakings. A successful partnership affiliation will remove barriers to CCT participation for both physicians and patients and expedite access and accrual. Support is available. To get started, ask your potential partners these questions:

- What training is available to community-based patient advocate groups and your outreach staff to leverage awareness building?
- Is education available for clinicians and staff on CCT processes and procedures?
- What infrastructure and support will be provided by the clinical trials support staff?
- Is help available achieving your accreditation requirements?
- What financial support is available to clinicians participating in CCTs?
- How will CCTs help you achieve regulatory compliance?
- Is there support for credentialing and auditing?
- How will clinicians be informed and educated about specific trial protocols?
- Is there a PI mentoring program?
- What technology is available to improve efficiency (telemedicine, EMR flags, recruiting apps, guidelines and pathways/decision support, etc.)?
- Are there tools for collecting, analyzing, and reporting required information?
- What role will local physicians play on tumor boards and conferences?
- What support is provided to ensure that patients are able to comply with protocols?

This affiliation evaluation process is adapted from the ENACCT 360° CCT Assessment and Improvement Protocol in which ENACCT conducts individual and group interviews with a cross section of leaders and staff in an affiliation with a research-based cancer center. Relevant data and documents are collected and analyzed in order to identify gaps and weaknesses in the CCT process and recommend strategies for improvement. A similar online self-assessment will be available for community cancer centers in 2013.

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