



Association of American Cancer Institutes COMMENTARY

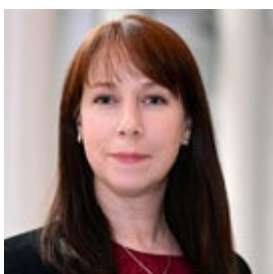
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Integrating Clinical Research into Clinical Care

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One of the biggest challenges facing clinicians is integrating clinical trials into patient care and avoiding interruptions which slow the flow of busy patient clinics, compromising trial efficiency and compliance. Though every clinic is unique, best practices can be implemented before, during and after a patient's visit to make conducting clinical studies much simpler.

Before the visit

Many clinical trial offices conduct feasibility reviews before study initiation. While such reviews can be time consuming, they can head off trials that may not adequately address the patient needs at a given cancer center. Careful evaluation of the patient population and honest assessment of whether an investigator sees those patients in clinic can help a trial meet its accrual goals.

Evaluating competing studies for the same patient population and identifying the resources needed for regulatory management and nursing and coordinator support is also critical. Departments such as the investigational drug service or pharmacy, the outpatient infusion center and the laboratory should be carefully evaluated for their capacity to handle a trial. It is also important to ascertain level of interest among co-investigators and to enlist support from other essential clinical services like surgery, radiation oncology, radiology and pathology.

For better or worse, conducting clinical trials has become a large and complex business operation. Having savvy clinical trials finance officers who can handle trial coverage analysis and negotiate budgets and

[Commentary Overview](#)

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* Careful evaluation of the patient population and honest assessment of whether an investigator sees those patients in clinic can ensure that a trial meets its accrual goals.

* In preparing for a patient's clinical visit, trial coordinators should review upcoming clinic schedules, discuss potential trial enrollees, and have consent forms ready for potential subjects.

* A good rule of thumb to improve clinic flow is to see research patients early in the clinic schedule to avoid delays for other patients who are seeing their physician or receiving treatments.

About AACI Commentary

As part of AACI's efforts to feature the work and views of its member centers, AACI publishes *AACI Commentary*, a quarterly editorial series. Written by cancer center leaders, each edition focuses on a major issue of common interest to AACI cancer centers.



contracts can free physicians to manage patient care. Knowledgeable finance staff develop trial budgets which compensate research efforts and often identify hidden costs such as training staff to manage multiple sponsor portals and databases. Expert regulatory support is also needed to ensure approval from all required institutional committee reviews. Conducting your own local site initiation visit, even if a pharmaceutical company has done its own, can iron out site-specific conflicts and identify “who does what” for each patient visit. Doing your homework prior to study initiation pays dividends once the study starts.

During the visit

In preparing for a patient's clinical visit, the investigator and/or coordinators should review upcoming clinic schedules, discuss potential trial enrollees, and have consent forms ready for potential subjects.

In most clinics, while the physician explains the study and answers questions from the patient and their family, it is the research coordinator who does the administrative work-- obtaining signatures, copying consent forms and providing documentation in the medical records. Having a discrete area set aside for the trial coordinator to complete their tasks not only allows a thorough review of the consent process but promotes positive working relationships between staff and coordinators.

Once a subject is enrolled, coordinators should prepare a written “research order” to help the investigator know which tasks need to be accomplished at each visit, including tests and documentation. If time allows, identifying and categorizing adverse events in the clinic can save time later in the trial and improve data reporting accuracy.

A good rule of thumb to improve clinic flow is to see research patients early in the clinic schedule to avoid delays for other patients who are seeing their physician or receiving treatments. Such scheduling can also avoid the need for clinic staff to stay past their normal working hours. This also applies to patients who may need to be re-consented when protocols are amended, or require an unscheduled visit.

After the visit


Reviewing eligibility and registering patients should generally be done outside clinic time to ensure that these important steps are carefully conducted. In addition, with the growing number of sponsor portals and clinical trial management databases, data entry is also best done away from the clinic.

Post-award financial management begins with flagging research patients in the electronic medical record. Research coordinators should be trained to review billing in the context of determining what constitutes research care versus routine procedures and visits. A

completed pre-study trial coverage analysis helps with correctly assigning completed services to enhance billing compliance. Similarly, effective, consistent communication between the finance team and the research coordinator leads to better billing, fewer penalties resulting from inaccuracies, and timely payment.

A final word about sponsors and monitors. The frequency of site monitoring visits should be defined in the trial contract so that investigator and coordinator efforts are adequately compensated. Monitoring visits should be completed away from the clinic to avoid distracting investigators from their clinical duties and to maintain patient privacy. In addition, investigator or research coordinator time devoted to working with monitors should be limited. We suggest that an institution's internal trial quality assurance or quality control officers help with preparing audits and trial remediation plans and provide ongoing clinical trials training.

Many sites are "pushing back" against sponsors' requiring third party review of investigator new drug safety reports when the drug is used in a different disease or drug combination. These reports require tremendous amounts of time for review and disposition by the investigator and research staff. Such reports are an example of non-value added work which takes the physician away from the clinic. We encourage cancer centers to develop internal policies that eliminate these unnecessary reviews.

Clinical trials are an essential element of the cancer care spectrum. Careful planning, preparation and trial execution, using the practices outlined above, can increase trial enrollment, promote efficient clinic operations, enhance clinical trial finance management and provide satisfaction for patients receiving research treatment. 

Representing 96 of North America's premier academic and free-standing cancer centers, the Association of American Cancer Institutes is dedicated to reducing the burden of cancer by enhancing the impact of leading cancer centers.
