The Nuts and Bolts of Clinical Research Billing

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While the Centers for Medicare & Medicaid Services' (CMS) national coverage determination policy on clinical trials essentially maintained the status quo for 2008, recent changes regarding Medicare billing of clinical research and the subsequent focus on the billing of patient care services have complicated the research regulatory environment. Significant improvements in compliance have been made in recent years, but the healthcare industry still struggles with effective oversight of clinical trial activities. Many healthcare organizations have difficulty integrating clinical research with other institutional priorities. In the community setting, multiple parties with research interests complicate the process even more. As a result, practices, hospitals, and academic medical centers that participate in research efforts are experiencing increased compliance and financial risk, as well as opportunity for financial reward.

Cancer programs lead the way in clinical research in many healthcare organizations, so research infrastructure is often housed within the cancer center. Today, many community cancer centers are evaluating policies and procedures to improve proper documentation and billing of payers, sponsors, and patients. Effective billing practices begin with the creation of a complete budget and continue with the establishment of internal controls for trial enrollment, billing, audit, and quality control. Coordination and buy-in of cancer center leadership and management are essential at every step of this process.

Organizational Structure and Financial Management

A strong organizational and management structure is a key driver of a research program's financial success. Oversight of research activities requires an element of coordination within the cancer program and among external departments and should be integrated with the cancer program's other major objectives. Research program managers must have clearly defined roles and manageable spans of control. In addition, research management should:

- Implement transparent procedures
- Understand and meet regulatory, compliance, and clinical requirements
- Monitor the financial performance of research activities.

Generally, cancer programs assign a research nurse coordinator to carry out many of these management duties under the direction of a principal investigator. One challenge for community cancer centers is to ensure that this infrastructure—which supports all of the administrative and financial functions—grows at the same rate as the research program. When research programs outpace their original infrastructure, a realignment and reinvestment in additional personnel and services are necessary. Cancer programs must be aware of this risk and plan accordingly. As research begins to spread within a hospital organization, the cancer program may find additional support under centralized clinical trial functions within the hospital or medical system.

In addition to strong organizational support, efficient and effective financial procedures are vital to sustaining a balanced research program. The following elements directly affect the research program's long-term success and stability and should be evaluated for optimal performance:

Accounting Procedures. Accounting for research trial activity is different from typical hospital or physician practice activities, with the added complexity of public (government) versus industry research trials. Best practices dictate that resources be aligned to support specific research accounting needs that are based on the level of activity. Standard practices related to budgeting, reporting, sponsor billing and reconciliation, and residual

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balances must be implemented to support trial activities.

Tracking Research Activity. While some cancer programs are investing in information systems designed for clinical trial activity, many still use spreadsheet and manual tracking systems. No matter which system your cancer program follows, research activities must be tracked in a centralized fashion and monitored for these components:

- Trial status (open, closed to accrual, closed)
- Patient accrual
- Key dates or deadlines in the trial
- Trial balances
- Other financial performance indicators.

Contract Management. Trained staff should negotiate contract terms, such as payment policies and conflict of interest language. Successful contract negotiations are based on a full understanding of the costs and operational requirements for performing the study. Generally, an individual trained to conduct clinical research negotiations works closely with the principal investigator to secure an optimal contract.

Performance Management. In addition to implementing certain financial policies and procedures, cancer programs must monitor and evaluate research performance. Specific examples of performance measures can be found in Table 1.

Getting Started: Creating a Budget

To obtain a clear understanding of the resources allocated to clinical research and the funding required to support research initiatives, cancer program leadership must create appropriate budget projections. A budget should be created for each type of trial, whether there is funding or not, to understand the financial impact of each protocol to the overall program. In other words, even if a cancer program participates mainly in the National Cancer Institute's (NCI) Clinical Trials Cooperative Group, attention to the financial and billing aspects is still critical. Reimbursement for these trials is more limited than with industry trials, so cancer program leadership must budget to offset costs related to staff salary and data management services. Often these research-related costs are paid out of operational or foundation funds.

The protocol, including detail on standard-of-care versus research-related activities, drives the development of a budget. Standard of care includes services that would take place as a result of a regular course of treatment for cancer care, and these services are billable to the both public and private payers. Non-standard-of-care or research-related activities cannot legally be billed to a government payer and should not be billed to a private payer—especially if the program is receiving reimbursement from the trial sponsor. With an industry trial, cancer programs can most likely recoup these costs by billing the sponsor.

Within the budget, identify specific personnel costs, administrative and institutional fees, and per-patient costs for each research activity or procedure. As appropriate, budget projections for research activities incorporate both physician professional fees and hospital charges. Standard research rates for hospital and physician services should be set at either the department or institutional level and should not change from trial to trial. Finally, implement a standard policy related to start-up costs, defining which are non-negotiable (e.g., IRB fees, administrative fees, and/or the first patient's full cost of treatments).

The principal investigator should review the proposed budget before submission to the sponsor, and have trained staff initiate negotiations related to budget and contract details. Cancer programs should develop standards related to budget preparation, format, signature or review process, and turnaround time (see Table 1). These standards, or best practices, must be communicated to research staff and monitored to meet performance expectations.

The Nuts and Bolts of Billing

Cancer programs must put controls in place to ensure that trial-related and standard-of-care charges are appropriately accounted for and billed. To successfully bill for services related to clinical trials, cancer programs should:

- Identify the research participant and facilitate front- and back-end revenue cycle procedures.
- Delineate between standard-of-care and research-related charges.

Table 1. Example of Performance Measures for Financial Management of Clinical Trials

Management of Account Set-up	Preferred	Acceptable	Not Acceptable
■ Budget creation	Within 1-3 days	Within 1-5 days	More than 5 days
■ Days for contract negotiation	Within 2 weeks	Between 2-4 weeks	More than 4 weeks
■ Timeliness of account set-up	Within 1-3 days	Within 1-5 days	More than 5 days
Management of Clinical Trial Accounts			
■ Timeliness of transactions	Less than 25% discrepancy	25% to 50% discrepancy	More than 50% discrepancy
■ Percentage of accounts in deficit			
● Total budget deficit	Less than 25%	25% to 50%	More than 50%
● Total budget and cash deficit	Less than 10%	10% to 20%	More than 20%
● Average number of consecutive months with projects in deficit	Less than 30 days	Between 1-3 months	More than 3 months

- Properly bill the trial sponsor, third-party payers, and/or patients for appropriate services.
- Incorporate audit or monitoring procedures to minimize errors and mitigate risks to the cancer program, practice, or hospital.
- Perform real-time financial management of clinical research accounts.

An example of a successful billing process model is found in Figure 1.

Although significant risk for errors exists throughout the process, cancer programs can take the following three steps to minimize risk and enhance collections:

Identify the subject upon enrollment and set-up the appropriate billing controls. When a patient is enrolled in a clinical trial, appropriate and accurate account set-up is essential to ensure correct billing. This process includes clear and correct identification of standard-of-care versus research activities. Typically, programs create a specific research card or study calendar to serve as a communication tool at the point of patient arrival or patient registration. Some programs even separate the research registration account from the patient's normal insurance account by creating different "cases" or "accounts" within hospital and practice scheduling and/or billing systems.

In most cancer programs, research billing procedures need to adapt to and support specific hospital or physician billing systems. Clear identification of research services on the encounter form or order sheet at the point of charge entry will help cancer programs correctly capture research charges. Some cancer programs have developed and implemented systems that use different-colored encounter forms with research modifiers or specific research labels. Other cancer programs enter orders and charges directly into the patient's research account within an electronic health record (EHR) system. Even if your cancer program participates mostly in NCI-sponsored trials, it is still important to have these systems in place. For example, although NCI will often supply the drugs for these trials, cancer programs must use the correct modifier to alert Medicare that administration services were conducted as part of the research trial. If no modifier is selected, cancer programs run the risk of Medicare denying payment of administration charges based on the lack of a corresponding drug charge.

Employ an audit mechanism (preferably electronic) to ensure appropriate billing of the sponsor and payer. Once clinical trial activities begin, automatic and electronic billing for standard-of-care activities is likely to occur as a result of routine billing processes. Cancer programs must put proper controls in place to ensure that bills are reviewed to guarantee accurate billing to the sponsor and payer, including coding (the payer bill requires unique coding for patients enrolled in clinical trials, such as Q1 modifiers or V-codes) and documentation. While many organizations institute policies and procedures that result in careful review of bills sent to sponsors for research-related activities, they often fail to institute a corresponding review of the concomitant bills for payers and patients related to standard-of-care activities. This lack

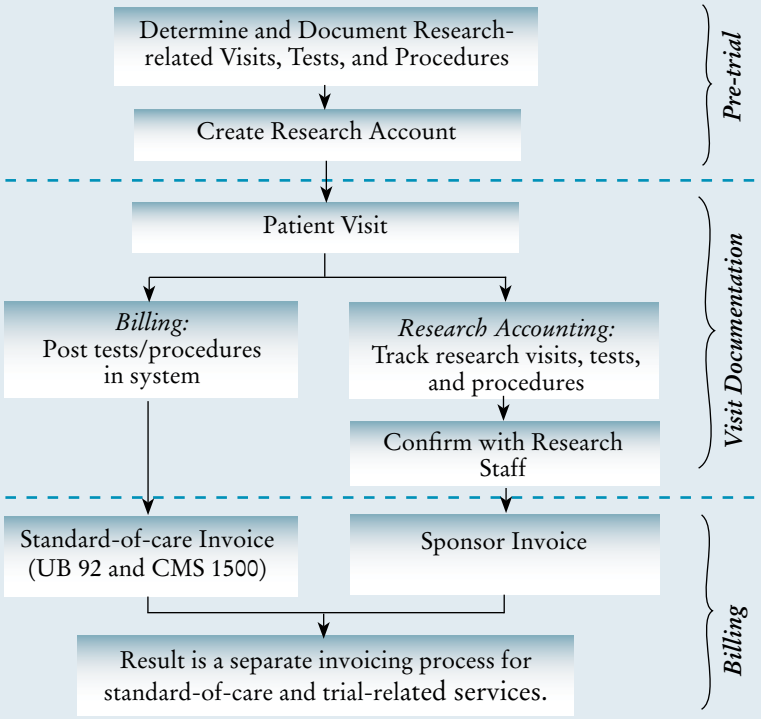
6 Characteristics of *Successful* Clinical Research Programs

1. Provides a market-leading value to patients, physicians, payers, and other stakeholders.
2. Develops a heightened market presence.
3. Attracts patients and top-notch physicians.
4. Drives downstream referrals and revenues.
5. Serves as the focus of planned giving and other philanthropic efforts.
6. Generates an acceptable return on the financial investment.

5 Characteristics of *Unsuccessful* Clinical Research Programs

1. Excludes clinical research when developing and evaluating institutional goals and objectives.
2. Fails to assign responsibility for the management of clinical trials beyond Institutional Review Board (IRB) review.
3. Uses non-standardized administrative, operational, and billing processes.
4. Fails to provide adequate training and information resources.
5. Fails to periodically review procedures to ensure financial and regulatory compliance.

Figure 1. Model Billing Process for Clinical Research Program



of coordination leads to increased compliance exposure and financial risk for an institution.

A comprehensive audit process checks the quality and accuracy of subject identification, registration, and charge entry for *both* standard-of-care and research-related activities. Depending on the volume of clinical trial activities, organizations that have implemented best practices regarding clinical trial billing have instituted processes that include a concurrent review of bills to sponsors, payers, and guarantors related to the same episode of care. This practice not only provides a real-time check of the accuracy of the accounts, but also encourages information and outcomes to be shared across front- and back-end billing staff to continuously monitor and improve performance. The scope of this process is often determined by an organization's resources and clinical research activities; and, while it is least risky to audit every bill associated with a research patient, this task may be difficult and resource intensive. Electronic resources can be used to facilitate the audit, or cancer programs can choose to audit a certain percentage of research patient accounts.

Specify payment procedures and support with proper controls. Cancer programs must establish a process to account for research payments. Proper controls should be in place to direct payments back to the research account. Clearly articulated procedures should be stated within the contract to indicate proper controls, such as requiring the sponsor to include the account number on the payment check. Many cancer programs need to work with their accounting departments or grant administration to facilitate the timely deposit of payments. Finally, program management can limit increases in account receivables by monitoring account balances, patient accruals, and payment terms for each research trial in standard, periodic reports.

Audit Your Process and Performance

Cancer programs should implement a regular audit process—not only to review the billing function but also to evaluate financial performance and contract management of their clinical research program. During this review process:

- Review clinical trial contracts and policies related to processing trial patients, visits, and billable procedures.
- Conduct interviews with key research program staff members.
- Review the process flow of documentation related to service, coding, registration, and billing.
- Analyze clinical trial accounting, coding, and billing processes and procedures.
- Examine charge sheets, research registration cards, and other mechanisms for accurate charge capture during the charge entry process.
- Audit select research accounts and billing records. This three-step process should: 1) include a sample of active and past years' accounts and protocols; 2) compare accrual information and protocol documents to funds billed and received; and 3) review invoice details to confirm that services were not billed to Medicare or other third-party payers in error.
- Document findings and discuss them with a multidisciplinary group that includes members from research staff, principal investigators, revenue cycle staff, and management (in coordination with internal legal counsel).

The audit process helps a cancer program stay on point as new research is pursued, the funding mix changes, or the program experiences management and/or staff transitions.

You Can *Succeed*

The billing process for clinical trials is complex. In cancer care, the clinical trials themselves are quite complex. Within any trial, therapies, drugs, devices, tests, and evaluation and management activities must be clearly identified as either standard of care or in direct support of the clinical trial. To start, evaluate your cancer research program by answering five questions:

1. Are resources available and aligned to support growth in clinical research?
2. Are research procedures clearly integrated throughout the clinical enterprise?
3. Is budget development executed under standard policies and/or procedures?
4. Are systems in place to identify enrollees, appropriately charge sponsors or third-party payers, and track revenue back to the research account?
5. How is the program performing financially?

Strong leadership, clear and transparent procedures, and effective process controls are essential for cancer programs to successfully navigate the regulatory and compliance challenges related to clinical research.

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