Developing an Investigator Site Budget for Clinical Trials

Many community oncology practices become involved in pharmaceutical industry-sponsored clinical trials for two good reasons: to supplement their menu of clinical research projects and to expand treatment options for their patients. Expectations of the site's investigators are that the sponsor will cover the costs of performing the research. While major research programs in academic centers can sometimes shift costs or cover the costs with philanthropic or other sources of income—making the research project appear to make a profit or at least break even—private practices usually do not have this ability, given the current structure of third-party reimbursement.

The Center for Cancer Care and Research (TCCCR) of St Louis, Missouri, is a Clinical Trial Award–winning practice and a member of the US Oncology Network (Houston, Texas) and participates in clinical research through US Oncology Research. The practice also participated directly with pharmaceutical sponsors, and it is a member of the Heartland Cancer Research Community Clinical Oncology Program (St Louis, Missouri).

TCCCR has found that developing a site budget that captures all of the costs associated with the trial and using the budget to negotiate expense coverage with the sponsor is critical to ensuring the appropriate funding support for a trial. Sponsors must provide funding for protocol requirements that exceed the standard of care.[1,2] These procedures may include additional lab testing, extra radiology procedures to confirm response at predetermined intervals, and tests for specific toxicities expected with the study drug. During the budget development process, it is important to identify these protocol-specific testing requirements. In addition, determine what routine patient care costs Medicare or private insurance carriers in your state will cover, and set up appropriate billing processes for the nonroutine patient care costs. Most sponsors pay these costs through an invoicing process, but the cost must be determined prospectively and negotiated.

The optimal conduct of clinical research in any setting requires dedicated research staff. Having such staff increases the likelihood of success adhering to protocols and providing the best patient care. When budgeting for staff time, consider the time required for all tasks integral to coordinating the trial: screening patients, obtaining informed consent, conducting patient visits, completing accurate source documents and case report forms, maintaining regulatory documents, and communicating with the sponsor and contract research organization. Reimbursement for those costs should be included in a budget.

TCCCR has designed an Excel template that reflects the true cost of conducting research by including these so-called hidden costs in the budget request (Table 1). The template takes into consideration fees for research personnel at all levels, including the principal investigator, site manager, clinical research coordinators, and regulatory coordinators. The template is designed to determine reimbursement per cycle with a separate entry for screening procedures rather than being based on a flat per-patient fee. This methodology provides site compensation for those patients who remain enrolled onto study for an extended period of time, and it protects the sponsor from paying a full per-patient fee for those patients who only receive one or two cycles of treatment. As with all documents related to research, the template is a work in progress—ever changing to incorporate additional fees as they become apparent and appropriate.

TCCCR has a separate Excel template for budgeting nonrefundable study start-up fees. It has proved to be a valuable tool, as it documents the costs incurred by the site, even in the event that no patients are enrolled (Table 2). In the past, sponsors would reimburse for study start-up fees, but now, sponsors are almost always willing to approve such payment.

Budgeting for payment of investigator and coordinator salaries during attendance at investigator meetings remains controversial. Because the site must pay its staff during these meetings, TCCCR believes that the sponsor should be charged for the salaries and benefit costs associated with attendance. Often, the practice is told that attendance at an investigator meeting is "the cost of doing business." However, investigators and coordinators attend these meetings specifically for training related to the sponsor's clinical trial. Therefore, these meetings are more appropriately considered to be the sponsor's cost of doing business. Perhaps if site managers unite on this issue, a change can be effected.

Other site costs that should be considered during budget development, and that are included in TCCCR's template, are

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Table 1. Study Budget

Budget Item	Physician/ PI	Site Manager	CCRC 1	CCRC 2	Regulatory Coordinator
Informed consent	0.5	0	2	0	0
Screening procedures					
Weekly screening log faxed	0	0	0.5	0.5	0
Weekly phone call to review screening activities	0	0	0.25	0.25	0
Medical history review	0.5	0	1	0	0
Inclusion/exclusion criteria review	0.5	0	1	0	0
Review previous and concomitant medications	0.5	0	1	0	0
Review demographics	0	0	0.5	0	0
Requires central lab submission	0	0	1	0	0
Requires tissue submission	0	0	1	0	0
IVRS screening registration	0	0	0.25	0	0
Central review of eligibility	0	0	0	0	0
Central review of eligibility with documentation	0	0	0	0	0
Radiology review of disease status	0.5	0	1	0	0
Order study drug	0	0	0.5	0	0
Drug accountability	0	0	0	0	0
Total hours	2.5	0	10	0.75	0
Cost, $	437.5	0	500	37.5	0
Total per screening visit, $	1,170.00				
Subject visit—cycle 1					
Subject interview	0.5	0	1	0	0
Review and record concomitant medications	0.5	0	1	0	0
Review and record adverse events	0.5	0	1	0	0
Schedule return visit	0	0	0.5	0	0
Schedule protocol required procedures	0	0	0.5	0	0
Complete source documentation	0	0	0.5	0	0
CRF completion	0	0	1	0	0
Radiology review, tumor measurements	0	0	0	0	0
Central lab collection and shipment	0	0	1	0	0
Obtain and ship central radiology review materials	0	0	1	0	0
Pharmacokinetic specimen collection and shipment	0	0	0	0	0
Order study drug	0	0	0.25	0	0
Drug accountability	0	0	0.25	0	0
Monitor visit	0	0	0	0	0
Preparation of informed consent log	0	0	0.25	0	0
Preparation of enrollment log	0	0	0.25	0	0
Maintain regulatory documents	0	1	0	0	1
Invoice sponsor for NSOC procedures	0	1	0	0	0
Total hours	1.5	2	8.5	0	1
Cost, $	262.5	130	425	0	20
Total per minor cycle, $	1,005.00				
Subject visit—cycle 2					
Subject interview	0.5	0	0.5	0	0

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Table 1. Study Budget (continued)

Budget Item	Physician/ PI	Site Manager	CCRC 1	CCRC 2	Regulatory Coordinator
Review and record concomitant medications	0.5	0	0.5	0	0
Review and record adverse events	0.5	0	0.5	0	0
Schedule return visit	0	0	0.5	0	0
Schedule protocol required procedures	0	0	0.5	0	0
Complete source documentation	0	0	0.5	0	0
CRF completion	0	0	1	0	0
Radiology review (tumor measurements)	0.5	0	1	0	0
Central lab collection and shipment	0	0	1	0	0
Obtain and ship central radiology review materials	0	0	1	0	0
Pharmacokinetic specimen collection and shipment	0	0	0	0	0
Order study drug	0	0	0.25	0	0
Drug accountability	0	0	0.25	0	0
Maintain regulatory documents	0	1	0	0	1
Invoice sponsor for NSOC procedures	0	1	0	0	0
Monitor visit	0.5	1	4	0	1
Total hours	2.5	3	11.5	0	2
Cost, $	437.5	195	575	0	40
Total per major cycle, $	1,497.00				
Subject follow-up					
Subject contact, office visit or phone call	0	0	0.5	0	0
Source documentation	0	0	0.25	0	0
CRF completion	0	0	0.25	0	0
Radiology review, tumor measurements	0.5	0	1	0	0
Central lab collection and shipment	0	0	1	0	0
Maintain regulatory documents	0	1	0	0	1
Total hours	0.5	1	3	0	1
Cost, $	87.5	65	150	0	20
Total per follow-up visit, $	387.00				
Other direct study-related activities					
Screen fail fee, invoiced, $	1,000.00				
Fee schedule, $ cost/hour					
PI	175.00				
Subinvestigator	100.00				
CCRC	50.00				
Site manager	65.00				
Regulatory coordinator	20.00				
Overhead, %	20				

NOTE. Table depicts an example of a spreadsheet for clinical trial conduct, which includes estimates of the time spent for each activity. Users can substitute estimates of personnel costs to calculate their specific study conduct costs.
Abbreviations: PI, principle investigator; CCRC, certified clinical research coordinator; IVRS, interactive voice response system; CRF, clinical research facility; NSOC, network and security operations center.

site initiation meetings, completing and faxing screening logs, third-party radiology review, central lab specimen collection and shipment, the complexity of the case report form, the frequency of monitoring visits, collection and shipment of pharmacokinetic specimens, conducting the close-out visit, and long-term storage of study documents.

Table 2. Study Start-Up Budget

Budget Item	Site Manager	Regulatory Coordinator	CCRC 1	CCRC 2	Physicians
Protocol feasibility meeting	2.00		1.00	1.00	1.00
Feasibility questionnaire completion	1.00				0.50
Pre-study site visit	8.00	1.00			1.00
Prepare, distribute, and collect financial disclosure documents		1.00			0.50
Preparation of regulatory documents	2.00	3.00			
Budget review and preparation	4.00				1.00
Contract review	3.00				1.00
Set up contract accounts	1.00				
Preparation and coordination of central radiology review requirements					
Preparation of protocol-specific documents					
IRB submission					
Local IRB					
Central IRB	1.00	2.00			1.00
Accounting and invoice preparation	2.00				
Organize regulatory file, prepare CCRC study conduct file	2.00	3.00			
Organize and verify receipt of study supplies and drug			2.00	2.00	
Investigator meeting			16.00		16.00
Site initiation visit	8.00	2.00	8.00	8.00	1.00
Site training of ancillary staff, RN, pharmacy, etc.	4.00		4.00	4.00	
Sponsor correspondence/discussion during start-up process	2.00	2.00			
Total hours	40.00	14.00	31.00	15.00	23.00
Cost, $	2,600.00	224.00	1,240.00	600.00	4,025.00
Long-term storage of study documents cost, $	600.00				
Total study start-up cost, $	9,289.00				

NOTE. Table depicts an example of a spreadsheet for clinical trial startup, which includes estimates of the time spent for each activity. Users can substitute estimates of personnel costs to calculate their specific study initiation costs.
Abbreviations: CCRC, certified clinical research coordinator; IRB, institutional review board.

A discussion of budgeting at the site level for clinical research would not be complete without discussing overhead costs. At TCCCR, the research staff and accounting staff have worked together to establish overhead at 20% of operating costs. Overhead includes such things as rent for space, copy machines and the accompanying service agreements, printers, print cartridges, paper, computers, information technology support, courier services, postage, and mileage.

In summary, it is essential for a community oncology practice to be aware of all the costs associated with conducting clinical research and have the ability to document those costs to validate budget requests. Expect sponsors to negotiate on funding support, but consistently resist making budget reductions that are unreasonable. Ensure that budget and billing procedures are in place before a trial begins and that all staff, not only research staff, remain diligent in accurately budgeting and billing for research procedures.

Oncology clinical research is vital to the goal of improved survival, diminished treatment toxicity, better quality of life, and, yes, cure. However, considering today's economic environment, the complexity of clinical research and ever-mounting regulatory demands, investigative sites may be shying away from research involvement due to the site-level cost. The oncology community, physicians, nurses, other research staff, and industry sponsors must all work together to ensure a mutually beneficial economic arrangement in which everyone—especially the patient—benefits and makes reaching goals a reality.

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References

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