



By Steve Stoller, PhD, MPH

Financing Clinical Trials Research at Kaiser Permanente

Abstract

Kaiser Foundation Research Institute (KFRI) has developed and implemented in the Kaiser Permanente (KP) Northern California Region a comprehensive system for assessing and budgeting costs of clinical trials and for negotiating study budgets with research sponsors. KFRI has shared its methodology and results with research leaders throughout KP. This article communicates the background and current status of this effort to the KP research community at large and specifically to all KP physicians interested in clinical trials research. KFRI hopes to benefit KP as an organization by giving its current and future researchers a deeper understanding of the economic and financial factors underlying clinical trials and the importance of using a systematic approach to developing and negotiating research budgets.

As a research organization, KP has unique strengths as well as unique financial concerns. This article presents basic economic and financial concepts as the basis for understanding cost assessment and the logic of budget development. Some key elements of successful negotiation strategies are also presented.

Prospective KP principal investigators are urged to take a systematic approach to assessing and budgeting the costs of clinical trials. KFRI is prepared to assist KP physicians with this task and to negotiate industry-sponsored clinical trials budgets with sponsors.

“The clinical trial process is the most objective method ever devised to assess the efficacy of a treatment. It is expensive and slow, and in need of constant refinements and oversight, but the process is trustworthy.”

—Justin A Zivin, “Understanding Clinical Trials.”^{1:75}

Introduction

Economists are fond of reminding us that “there is no such thing as a free lunch”—someone ultimately pays. Similarly, there are no free clinical trials: Demonstrating that a promising molecule is a safe and effective therapeutic agent is enormously costly. In addition to incurring direct laboratory and clinical costs, clinical trials must meet ever-increasing requirements of regulatory compliance as well as bear public scrutiny of the clinical trials process. In practice, the cost of developing new drugs and investigational devices will have been paid jointly by the sponsoring pharmaceutical company, the clinical research site, and the patient’s third-party insurer.

In the past year, the Kaiser Foundation Research Institute (KFRI) has been grappling with an important health care issue: how to fairly and accurately assess and charge to research sponsors the costs of resources used in conducting clinical trials at Kaiser Permanente (KP) facilities. As a not-for-profit organization, our goal has been to avoid subsidizing the product development expenses of the US pharmaceutical industry, an industry which includes manufacturers of medical and surgical devices as well as manufacturers of drugs. The US pharmaceutical industry earns a 20% profit margin on sales—a figure three times the average for US industry as a

whole—and a consistent 30% return on equity (a figure four to five times the US average).^{2,3}

Participating in Clinical Trials: KP’s Unique Position

KP is in a unique position in the US clinical trials “industry” in as much as KP differs from academic medical centers (which have clinical trials research at the core of their activities) and freestanding research sites (which may range in size from small, single-specialty medical practices to large, multipractice associations and networks). Academic and freestanding research sites typically construct their budgets to encompass the stipulated research and administrative “protocol-induced” activities.

Compared with KP, academic medical centers and freestanding research sites have in common a greater capacity to pass through to third-party payers the cost of routine clinical care mandated by clinical trials. Routine clinical care (as broadly defined) is billed to the research subject’s insurer, whereas nonroutine clinical care (as narrowly defined) frequently is reimbursed by study sponsors at premium rates and serves as an additional source of profit for these institutions. However, for patients with a given medical condition, care defined as “routine” or “standard” may vary substantially by geographic region and by type of provider institution; no bright line

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distinguishes routine care from protocol-induced care. The research site stands at arm's length from the patient's insurer, but clinical costs may be accepted by the payor as representing either routine care or care needed for treating the patient's condition. Historically, this transfer of costs to the payor has often occurred without the patient's insurer having explicit knowledge that the insured person has received treatment in the context of a clinical trial.

Because KP is its own third-party payor, we frequently find ourselves having to absorb internally the broader definition of routine care services as well as the costs of these services. This financial practice would make unattractive to us a budget which an academic institution would find attractive—and would thus place us at a comparative disadvantage in competing for promising studies.

However, on the positive side of the equation, KP stands in the unique position of having a heterogeneous, ethnically diverse patient⁴ population which is nonetheless homogeneous in representing the US Census block population at large. Patients are selected for participation in clinical trials across a broad range of specialties in our not-for-profit HMO, which has a well-deserved reputation for delivering high-quality medical care to its members. Compared with its research competitors—academic medical centers and freestanding research sites—KP may face a cost disadvantage, but this disadvantage is more than outweighed by KP's qualities as a research site superbly attractive to pharmaceutical company sponsors.

Indeed, KP differentiates itself from academic medical centers involved in the clinical trials indus-

try in an important respect: KP has direct access to its patient population as well as outstanding data systems and quality of patient care. Historically, academic medical centers have sometimes obtained first access to promising trials partly because of an implicit promise that KP patients would be referred to enroll in the trial. In these instances, KP has suffered financially through its role as a “secondary supplier” of research subjects.

KP distinguishes itself from academic medical centers also through KP's ability to enroll large numbers of patients in phase III randomized trials of a new drug where the control arm of the trial is standard therapy. Academic medical center research sites that collect subjects via referrals from community physicians are comparatively disadvantaged: When potential study subjects cannot be assured of receiving the investigational therapy, these patients' regular physicians have no pressing clinical or financial incentives for referring the patients to an academic medical center. Because KP provides substantial economy of scale in data collection at a single site and can assure the quality of data obtained, KP stands in a uniquely strong position for attracting this type of clinical trial.

Identifying the Full Costs of Clinical Trials

The first step in being able to charge research sponsors fairly for the cost of clinical trials is to identify the costs within KP. This is a challenging undertaking in an organization the size of KP, where the health insurance function is integrated with delivery of medical care to Health Plan members and where the mix of institutional and administrative costs is com-

plex. Paradoxically, the more integrated the functions of the institution (integration arguably creates real economic efficiencies for a “health care delivery system” such as KP), the more difficulty in identifying precisely the microcost of each service delivered. Difficulty arises from inconsistent data capture across a large organization such as KP and from questions concerning systematic allocation of institutional overhead costs.

Direct vs Indirect Costs

For financial analysis of clinical trials, costs are broken down into direct and indirect components. Direct costs include costs of specific clinical procedures and costs of the research and administrative activities required by the study protocol. These activities are often referred to as “protocol-induced” activity, although the term properly includes also those clinical procedures mandated by the protocol and extending beyond standard care. Indirect costs are the costs of supporting KP's research infrastructure, which includes such diverse elements as ensuring compliance with FDA regulations, obtaining all necessary approvals from the Institutional Review Board (IRB), and developing information systems for accurately tracking clinical activity, billing sponsors, and making sure that funds received are properly allocated within the KP organization.

Indirect cost charges designed to underwrite—and thus support—the organization's research infrastructure are a typical feature of all research budgets whether for pharmaceutical company-sponsored clinical trials requiring human subjects or for epidemiologic studies involving retrospective database analyses. Research sponsors



accept indirect costs with the knowledge that these costs are inherent in necessary administrative activities of research: ongoing regulatory oversight and compliance, legal and contractual functions, accounting, management of funds, and long-term investment in data systems and in the personnel education crucial to maintaining a viable institutional research program. Indirect cost charges are generally allocated as a percentage of either direct personnel costs or, alternatively, as a lower percentage of total costs. The controlling factor in applying indirect cost charges is the set of Federal regulations mandating uniform application of indirect cost methodology across the institution's research portfolio. The Federal regulations covering indirect cost charges are contained in Office of Management and Budget [OMB] Circulars A-21, A-122, A-87, and A-133 (Revised).⁵ Direct costs are further broken down into variable and fixed components. Fixed costs are commonly referred to as "overhead"; in the present analysis, however, fixed costs are distinguished from the indirect costs of maintaining KP's research infrastructure. An example illustrates categories of costs: The physician time and medical supplies required for initially obtaining a medical history and conducting a physical examination—activities typically performed in all clinical trials—are referred to as variable inputs, whereas the KP facility where the visit takes place uses resources (eg, electricity, water, housekeeping services) which are referred to as fixed inputs because they are both purchased and used by and for the entire facility. Nonetheless, a portion of these fixed inputs (and their cost) is properly allocated to obtaining the medical

history and conducting the physical examination.

More specifically, if the full cost of an initial 60-minute history-taking and physical examination is estimated at \$255 on the basis of a standard fee schedule, the cost of physician time would be approximately \$140; the facility resource, \$90; and KP administrative overhead, \$25.⁶ Cost of physician time is variable. Cost of facility resources includes variable costs (eg, medical supplies used directly in the provision of the service) and fixed costs (eg, electricity, water, housekeeping) allocated to the service. KP administrative overhead is another fixed cost, a portion of which is allocated to the service.

The per-patient direct costs plus indirect costs equal the total per-patient rate for the study. To this rate must be added specific per-study charges such as IRB submission and annual maintenance fees; fees for pharmacy setup to accommodate both the physical handling of an investigational drug and the FDA-mandated data recording; recruitment of study subjects; advertising; any special supplies and equipment required; travel; personnel time spent at investigator, study initiation, and other training meetings and with study monitors; and costs of the publication process. This list is not exhaustive. In addition, each study may necessitate unique "one-time" tasks, which must be recognized and accounted for accurately. At KFRI, identifying these costs is an ongoing effort.

Cost Accounting at KP

Moving from the theory to the practice of cost accounting is a giant step and is often easier in small organizations than in large ones. For example, a three-physician research site may have an

excellent grasp of its personnel cost, cost of supplies, and overhead costs while accurately allocating shares of overhead to specific clinical and research activities. In contrast, the task of accurately determining unit costs can be daunting for a "system" like KP, which has historically integrated three diverse activities: provision of health insurance to members; delivery of medical care through a "group-model" medical practice; and physical investment in hospitals, outpatient facilities, and laboratories.

To determine costs accurately, KFRI has examined several sources of cost data, including the CMIS database—KP's internal cost accounting system in the Northern California Region. The CMIS database has provided valuable input for cross-validation, but we have resisted relying on it exclusively out of concern for whether all KP administrative overhead has been allocated to unit costs as well as over concern about the systematic capture of data across all KP facilities. Progress toward more systematically reliable internal cost accounting data would assist the budgeting process, but broader questions of whether "economic cost" is being captured will always remain; an example is whether accounting measures of fully allocated cost (because they are historically derived) include an adequate component for future capital investment requirements.

In a straightforward approach to costing, KFRI developed an application of the CPT-4 (Common Procedural Terminology) coding system to describe the activities of clinical trials. Developed by the American Medical Association in the late 1960s as an identification system for reporting medical services and procedures, the CPT

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methodology was designed “to provide a uniform language that will accurately describe medical, surgical, and diagnostic services and ... provide ... communication among physicians, patients, and third parties.”^{7,iii} To recapture the costs of providing specific services to non-KP members on a “fee-for-service” basis, we attach to the relevant CPT codes the KP Fee Schedule charges developed by the Health Plan’s Northern California Patient Business Services Department. We reference these charges to market reality by looking at a database of “customary and reasonable” (C&R) charges ranked by percentiles for three-digit-zip code

geographic regions in which KP operates medical facilities.

For example, the KP Fee Schedule charge for CPT code 99205 (the 60-minute medical history-taking and physical examination for a new patient) is set at \$255, representing a weighted average of charges of the geographic regions in which the KP Northern California Region’s facilities are located.^{6,7} For comparison, for three-digit zip code 941__ (San Francisco), customary and reasonable charges for this procedure range from \$195 (50th percentile) to \$311 (95th percentile), and the 90th percentile is set at \$265.^{6,7} Examples of CPT codes, Relative

Value Units (RVUs), and fees charged at KP are given in Table 1.

The CPT-4 code/KP Fee Schedule methodology was designed with the expectation that a charge for a specific procedure captures the fully allocated costs of the entire KP Medical Care Program, including all administrative costs accrued by the Kaiser Foundation Health Plan. The intermediate link in this process is assignment of RVUs to each CPT code, thereby identifying separately the contribution of personnel time, physical resources, and administrative overhead to each procedure. This methodology (first developed at the Harvard School of Public

Table 1. Clinical trials procedures, CPT codes, RVU values, and KP fee schedule charges

	CPT-4 code ⁷	RVUs (Total Nonfacility) ⁷	KP Fee Schedule 2000 equivalent ⁶
Common clinical procedure codes			
Obtain medical history, conduct physical examination	99205	4.36	\$255
Conduct physical examination	99215	2.97	\$170
Monitor vital signs	99212	0.94	\$58
Placing 12-lead electrocardiogram	93000	0.79	\$98
Obtain chest x-ray film	71015	0.86	\$125
Obtain CT scan of abdomen with contrast medium	74160	9.09	\$1,410
Chemotherapy infusion (1st hour)	96410	1.65	\$224
Chemotherapy infusion (1+ hours)	96412	1.24	\$127
Procedure codes adapted to specialized research and administrative activities			
Obtain written informed consent	99499	N/A	\$265
Obtain inclusion/exclusion review	99080-22/99090-22	N/A	\$164
Adverse event monitoring, concomitant medication monitoring	99214	1.99	\$105
Phlebotomy/blood sample processing/conveyance to central laboratory	36415/99000	N/A	\$112
Investigational drug administration	90862	1.38	\$95
Data collection/management/reporting/archiving	99080/99090	N/A	\$126

Sources: Kaiser Permanente of California. Northern California Region. Patient Business Services. Nonmember Fee Schedule. [Oakland, CA: Kaiser Permanente of California]; 2000.⁶ American Medical Association. Current procedural terminology, CPT, 2000. Chicago, IL: American Medical Association; 1999. Further data available from author.

CPT = Common Procedural Terminology; RVU = Relative Value Unit; N/A = not applicable.



Health in the late 1980s) has been adopted by the Health Care Financing Administration (HCFA) and forms the theoretical basis of the Medicare payment system.⁸ The charge attached to a given procedure described by a CPT-4 code is designed to capture the full costs of the resources used in delivering the procedure. The language of CPT codes and RVU valuations is the lingua franca of health care finance outside the KP organization. Fully comprehensible to research sponsors, this language provides the basis for rationally discussing study budgets.

Outside the KP organization, variants of this budgeting approach are used by a wide range of research sites across the United States. Straightforward, generic logic is used both to describe relevant CPT-coded, protocol-mandated activities and to price those activities in a way that covers the full costs of their “production.” By referring to a standard fee schedule applicable to all external purchasers of clinical services in the KP Northern California Region, we at KFRI have tried to make the entire process as transparent as possible to sponsors of research. Our goal is to support the negotiation process by using defensible logic and standard charges. By adhering to a systematic approach for developing and negotiating all budgets for clinical trials, KFRI has introduced innovation to the area of budget strategy.

Accounting for KP Research and Administrative Costs

Although protocol-induced clinical procedures used in a clinical trial may be particularly expensive (eg, extra CT scans and multiple-gated acquisition cardiac blood pool imaging (MUGA) proce-

dures), we have clearly defined the methodology for characterizing these procedures and for accounting for their costs. A more complex task for administrators of clinical trials is to identify and allocate costs for the range of resources used in research and administrative activities. These costs cover diverse activities—eg, monitoring patients, assessing drug compliance and adverse events, data collection (sometimes an elaborate process), management-related functions, reporting, and archiving. All these activities use personnel and material resources and must be accurately accounted for if KP wishes to sustain a viable research program over the long term.

Sometimes a possible approach is to translate research and administrative activities into relevant CPT codes by using the same logic applied to the clinical procedures themselves. For example, obtaining informed consent from prospective patients and reviewing inclusion vs exclusion criteria are activities common to all studies that involve human subjects. Both activities require personnel time (typically, time spent by the principal investigator and by the research coordinator) as well as material resources and administrative overhead at the local facility. Each activity may be mapped to a relevant CPT code—a procedure that reasonably captures the resources required by the research and prices these resources accordingly.

This process fully captures relevant costs—some of which would not be included in estimates of personnel time only—and assigns research and administrative costs according to the per-patient rate required for the study. This process also allows inclusion of other important research and administra-

tive cost items that are not amenable to treatment on a per-patient basis—eg, Principal Investigator time and research coordinator time required at investigator meetings and at study initiation meetings; time spent with study monitors; time required for preparing Serious Adverse Event (SAE) reports and for complying with FDA audits; and time required for data analysis and for preparing (and then revising) materials for publication. If incurred, these costs must be both estimated and charged at an agreed-upon rate and either prospectively (ie, on a per-study basis) or retrospectively.

Negotiating Study Budgets: A Practical Approach for KP Researchers

Final study budgets are the result of negotiation between researchers and study sponsors. The first rule of successful budget negotiation is never to accept a sponsor's offer (ie, never “sign on the dotted line”) without first preparing and documenting fully your own budget and submitting both your budget and your terms to the sponsor. Be prepared to show the sponsor the logic and detail supporting the budget. KFRI has a library of budgets developed over the past year that can assist researchers with this task.

Another information source useful in preparing research budgets—and used widely by the pharmaceutical industry—is the PICAS (Pharmaceutical Information Cost Assessment Service), a collaborative database that contains detailed cost information for all research sites in the United States. To assist Principal Investigators in the sometimes complex process of preparing their own budgets, clients of PICAS are

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encouraged to prepare budgets proactively for their research sites and to submit them to research sites for signing. (For information on PICAS, see <http://www.dataedge.com/>.) PICAS is a tool sponsors use in an attempt to standardize their budgets to “industry average” costs. This practice works to KP’s disadvantage because KP’s costs are generally higher than the PICAS averages, principally because of KP facilities’ high-cost geographic locations. Moreover, because many KP budgets were estimated and negotiated on the basis of personnel time only, inaccurate KP cost data have historically been entered into the PICAS database. This factor has the effect of biasing the PICAS industry averages downward, an error we have been trying to rectify through ongoing communication with study sponsors.

You may discover that your carefully developed budget is a multiple of the sponsor’s offer. If this does not occur, you have probably omitted some relevant costs and should repeat the exercise of cost discovery described above. Clinical trials are inherently expensive when every detail is accurately accounted for, and often the research site finds itself in the position of having to run very fast to stay in place. At KFRI, our experience has shown that most research sponsors are prepared to negotiate budgets, but some are not. We try to negotiate openly with sponsors by presenting them full details of the costs underlying our budgets. We explain to sponsors that Northern California is a high-cost region of the country, and we point out KP’s substantial comparative advantages as a research site.

An important point to remember is that most sponsors (or their con-

tract research organization agents) need a sufficient number of patients, sufficient geographic and institutional diversity, and data of sufficient quality to make the clinical trials successful. Here is where KP’s advantages as a large organization come into play: We have a large and diverse yet representative patient population, outstanding clinical data systems, a reputation for excellent patient care, highly trained and dedicated staff, and a history of completing numerous clinical trials in multiple specialties. All these elements are valuable to the research sponsor. Above all, the critical importance of high-quality data should never be forgotten: The output of the clinical trial is data, and sponsors must therefore receive reliable data. Having to repeat a trial because data are questionable is not cost-effective!

The Endgame of Negotiation: Mutually Beneficial Compromises

Whatever short-term advantages sponsors might gain from an underpriced budget, they know that the research site must be economically viable if research is to be done over the long term. At KFRI, we try to reinforce this understanding as partners in ongoing clinical research.

Thus, for research sponsors, the clinical trial is ultimately a business decision. This fact should not be surprising—given that any rational business enterprise (here, the study sponsor) necessarily wishes to minimize its costs of conducting clinical trials research, without which the potentially promising new drug does not move on toward FDA approval. In addition, because the trial is so necessary, the rational spon-

sor is prepared to compromise on a final budget—as is KP.

Indeed, having determined the global parameters of cost recovery, we still have room for compromise, the extent of which should depend on carefully weighing pertinent nonfinancial factors: How will a particular trial change models of patient care at KP and benefit KP members and the community? Is the study at the forefront of research in a particular field and likely to enhance KP’s reputation as a research institution after results are publicized? Is the study a Phase-III study of an investigational drug, a phase-IV postmarketing study of an approved drug, a jointly (ie, Federally and privately) funded consortium, or a compassionate use study of an existing drug? Depending on the answers to these questions, different discounts from the economic budget may then be applied on a case-by-case basis. Participants in budget negotiations must also take into consideration certain limitations on bargaining power. For KP, drug costs provide an important example of such limitations: Although KP can certainly use its position as a massive purchaser of drugs to negotiate discounts from pharmaceutical manufacturers, this pricing is derived from market power—and pharmaceutical manufacturers do not on their own initiative develop favorable pricing for managed care organizations like KP.

Communication: An Essential Tool for Re-educating our Research Sponsors

With regard to clinical trials, the large pharmaceutical companies that operate as research sponsors have traditionally viewed KP as



something close to a free service. This view resulted primarily from two phenomena: lack of systematic communication between KP and sponsors (ie, to explain the unique elements in KP's structure) and an unsystematic approach for identifying costs and developing budgets. KFRI is trying strenuously to redress this situation through an ongoing communication and re-education effort with sponsors.

Part of this effort has involved submitting detailed "shadow" budgets to sponsors for every study that we evaluate—whatever the phase and however it is funded. In this way, we are trying to communicate KP's real cost position to sponsors and to encourage them to have these numbers entered into the PICAS database to more accurately represent the cost of conducting research at KP. This effort is bearing results: In the year 2000, the level of negotiated budget achieved across all medical specialties has been raised by a mean of 50% above the sponsor's initial offer. We are cognizant of the factors underlying KP's strong negotiating position and will continue to defend KP's interests with regard to our research sponsors.

How KFRI Can Help Principal Investigators at KP

Throughout our organization and elsewhere in the research commu-

nity, budgets must be developed that attempt to cover the full expenses of carrying out research at KP. At the same time, KP leadership has recognized that it is not equitable for a not-for-profit organization such as KP to use its member dues to subsidize the product development activities of the for-profit pharmaceutical industry.

With these factors in mind, KFRI is available to help at any stage of evaluating a study's financial feasibility. We can develop the total budget for the study according to the process outlined above. For industry-sponsored clinical trials, we will also act as the negotiating agent. For both these functions, we can supply a dimension of objectivity that even a financially trained Principal Investigator might lack in contemplating a clinical trial relating to his or her own specialty. KFRI will work with KP's legal staff to ensure that the clinical trial agreement contains appropriate budgetary contract language covering payment schedules, invoicing provisions, payment for optional procedures, and upfront payments to cover KP's risk of default or early termination by a sponsor. ♦

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Act

Act as if it were impossible to fail.

Dorothea Broude