

Clinical Research Site Overhead Costs

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In clinical research, overhead costs are the costs that cannot be directly attributed to a specific research study. Overhead costs are "pooled" into overhead accounts. These accounts are then charged to clinical studies or to other overhead accounts, which are themselves charged to studies. At the end of a financial reporting period, all overhead costs must be "absorbed" by some department or the organization as a whole.

Allocating overhead costs does not generate revenue. Its purpose is to give management the information it needs to make informed decisions about the business. Many organizations think they are making money on clinical research, but are actually losing money because they are not allocating costs correctly. This error often occurs when management assumes that a new activity, e.g., clinical research, generates incremental revenue and profits without increasing costs. This situation may be true briefly if there are underutilized people and space, but eventually, costs increase to support the additional revenue.

Very few clinical research costs can be directly attributed to a study. Examples include pass-through costs such as recruitment advertisement and lab fees. By far the largest cost, for personnel, cannot be charged directly. Personnel costs are pooled into overhead accounts and then charged to specific studies. The pooling process typically lumps together highly paid and low-paid employees to create a blended hourly rate. As a result, studies that require very experienced personnel may be charged the same hourly rate as those that can be conducted by beginners.

Overhead costs are often "fixed," meaning that they are incurred whether or not a specific study is conducted. Examples of fixed costs include rent and malpractice insurance. In contrast, "variable" costs increase or decrease with the volume of business. Examples of variable costs are syringes and office supplies. Over the long-term, most costs are variable. However, as John Maynard Keynes pointed out, in the long run, we're all dead, so the line between fixed and variable costs is typically based on the period in which management can adjust costs in line with changes in revenue.

Overhead costs are often "indirect," meaning that it is impractical to attribute them to a specific study. Theoretically, it is possible to track postage stamps and bookkeeping entries by study, but the tracking costs exceed the benefit. Some postage stamps and bookkeeping entries would have to be allocated to multiple studies, which is not practical. "Direct" costs are directly attributable to a specific research study and worth the trouble of tracking. Radiology tests are a good example of direct costs, especially when the tracking system already exists for other purposes such as patient billing.

Some costs are classified differently depending on the circumstances. For example, advertising for subjects for a specific study is a direct cost, while advertising for marketing purposes is an indirect cost.

Overhead accounts are allocated to research studies based on various metrics. For example, rent may be pooled with other facility costs and then allocated to the clinical research department based on the square footage used by the department. Facility costs may then be sub-allocated to individual studies based on revenue. As a result, a study that enrolls no subjects will get a free ride on facility costs, while high-enrolling studies pay more than their share. A more accurate method would allocate facility costs based on personnel costs

incurred by studies. Some studies consume more space because they have more documents, drugs and supplies than others, but just how precise should the allocations be? Some organizations are very precise, while others throw everything into a single overhead account.

To more accurately understand the full cost of each type of study activity, overhead costs can be allocated to activities with studies. For example, the cost of regulatory support correlates with number of study initiations, while the cost of subject recruiting support correlates with number of subjects screened; pooling these costs in one "study" overhead account hides important cost information.

Some overhead accounts may be allocated to other overhead accounts. For example, facility costs may be allocated to the accounting department, which then allocates its costs to a general corporate account, which then allocates its costs to the clinical research department. If clinical research is just one department in a larger organization, the allocation methods can have a major impact on the perceived profitability of the department. For example, if facility costs are allocated based on number of employees, a crowded clinical research office may be overcharged vs. a spacious medical laboratory with intensive utility requirements.

Calculating overhead rates can be a time-consuming process, so organizations typically calculate them annually for the following fiscal year. When a business changes, errors can creep into the numbers. For example, if the mix of inpatient vs. outpatient studies changes from year to year, overhead can be under- or over-charged. Accounting methods such as activity-based costing (ABC) more closely match overhead charges to actual business activity than more-simplistic accounting methods.

Study budgets are a mixture of direct, indirect, fixed and variable costs. For example, salaried clinical research employees are generally considered fixed, indirect costs, while contract personnel paid for actual hours worked may be considered direct, variable costs.

"Hidden" costs are not on the study budget but are nevertheless incurred by a clinical research site in the course of conducting the study. Hidden costs may consist of direct costs such as a control medication and overhead costs such as office supplies. Hidden costs can be attributed to specific studies or pooled into overhead accounts, which are then allocated to studies. Direct attribution provides a clearer financial picture for each study, but incurs more tracking and accounting costs than overhead pooling. In any case, regardless of a research site's accounting policies, costs are costs; if sponsors don't pay for them the site does.

Table 1 lists overhead costs that are common to clinical research sites.

Table 1. Clinical Research Site Overhead Costs

- Building:
 - Rent
 - Maintenance & repairs
 - Cleaning
 - Gas & electricity
 - Water & sewer
 - Trash collection
 - Security systems, locks & keys
- Clinic, Laboratory & Pharmacy:
 - Tools & equipment (purchase/depreciation, calibration & maintenance)

- Supplies (syringes, sample tubes, dry ice, etc.)
- Uniforms (purchase, cleaning & maintenance)
- Disposal of sharps and biological waste
- Thermometers and batteries (drug and specimen storage areas)
- Uncompensated medical care
- Office:
 - Furniture & equipment (desks, filing cabinets, photocopiers, etc.)
 - Computer hardware, software & network (purchase/depreciation, implementation, training & maintenance)
 - Telephone & fax (purchase/depreciation, connection, supplies & maintenance)
 - Office supplies (paper, toner cartridges, etc.)
 - Food and beverages
 - Postage & courier services
 - Internet connection & email
 - Website (create & maintain)
 - Record storage & disposal (non-study)
- Study Personnel:
 - Employee benefits (taxes, vacation, sick leave, insurance, parking, etc.)
 - Support time (staff meetings, reporting, communications, training, etc.)
 - Training (non-study)
 - Professional licenses
 - Certifications
 - Membership dues
 - Books & subscriptions
- Management & Support:
 - Clinical research support (marketing, business development, contracts, quality assurance, etc.)
 - Management personnel
 - Invoicing, collecting & financing accounts receivable
 - Insurance (malpractice/professional liability, general liability, property, etc.)
 - Study management software (purchase, implementation, training & maintenance)
 - SOPs (purchase, creation, maintenance & training)
 - Accreditation (fees and time)
 - Tax & other governmental filings (preparation & fees)
 - Other support (finance, human resources, legal, IT, etc.)
 - Institutional charges

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