wcg MAGI | Journal of Clinical Research Best Practices

Vol. 18, No. 4, April 2022 "Happy Trials to You"

Key Concepts in Financial Accruals for Clinical Trials

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There are two basic types of accounting: With cash accounting, we keep track of the cash that comes into and goes out each month. The difference is our net cash inflow or outflow for the month. With accrual accounting, we keep track of the amount we have earned and the obligations we have incurred during the month. The difference is our accrued profit or loss. Because the cash coming into and going out of our business (or household) often does not match the underlying activity, accrual accounting can be much more accurate than cash accounting.

This article expands on a previous article, "Financial Accruals for Clinical Trials – A Primer,"[1] with a discussion of seven concepts key to accrual accounting for clinical study sponsors:

- Accrual vs. cash accounting
- Simplicity and practicality
- The Sarbanes-Oxley Act (SOX)
- Perspective
- Auto-reversing entries
- Invoices as part of the accruals process
- "NAAP" ("No Accepted Accrual Principles")

Generally Accepted Accounting Principles (GAAP) require accrual-based accounting. It also provides tangible benefits, such as financial statements that more clearly reflect actual business activity and reduce the risk of financial surprises.

Although both revenues and expenses can be accrued, the focus of this article will be on study sponsor accruals for service provider and investigator site charges. Accruals are especially challenging for most industry-sponsored clinical trials because of their complex networks of external business partners (CROs, investigative sites, central labs, consultants, IRBs, etc.), highly variable levels of activity, and often complex payment terms.

Accrual vs. Cash Accounting

Suppose you start working on the first day of the month for a company that pays you $20 an hour and you get a paycheck every two weeks. Now suppose, after working 40 hours during the first week of the month, someone asks how much you have earned so far this month. Would your answer be (a) $800 because you have worked 40 hours or (b) nothing, because you will not get paid until next week? Most people would correctly answer (a) because when it comes to our salaries and wages, we naturally understand the concept of what we earn vs. what we are paid.

In contrast, when it comes to estimating clinical trial expenses, many people naturally think on a cash basis. When asked how much expense should be counted for a given service provider or site, your clinical manager's answer is often based on their estimate of the next invoice, and not what they estimate the service provider or site has earned for the period.

This approach helps estimate how much cash will be needed to pay your service providers next month, but it may only roughly correlate with how much they have earned this month. Because thinking in accrual terms does not come naturally to many people, patiently and repeatedly explain the concept to both your clinical managers and service partners. It may eventually sink in. How well they grasp the concept will directly determine the efficiency of your accruals process.

Simplicity and Practicality

Taken to the extreme, accruing for clinical trial expenses can be a huge effort. However, depending on the size of the company and the risk/uncertainty level it finds acceptable, this effort can be reduced to manageable levels. For example, some large companies simply use a straight-line methodology (dividing the total value of a contract by expected duration in months) when accruing for CRO and other external expenses. Although straight-line accruals may be imprecise, for a large company with a significant volume of contracts, the expenses can even out in aggregate

On the other hand, a small company with only a few large contracts may find straight-line accruals too inaccurate and opt for more granular, cost-driver-based models for service provider accruals. Common cost drivers include sites initiated, patients enrolled, case report forms received and monitoring visits conducted.

For any size company, expense accrual models should be as simple and practical as possible. Minimize the number of cost drivers and opt for those that are most easily obtained. The 80/20 rule applies to cost drivers: Twenty percent of the possible cost drivers probably deliver about 80 percent of the accuracy. For example, models driven simply by initiated sites and enrolled patients are practical because they predict billable activity fairly accurately and your clinical managers typically have these numbers handy in the normal course of business. However, if your models require significant time and effort every month from you, your clinical managers and your service providers, expect a frustrating experience.

No matter the quantity and types of accrual models you use, make every one of them as simple and practical as possible. The accrual models you should use depend on the size and scope of your company's operations, as well as the tolerance for uncertainty — and therefore risk — of your CEO and financial executives.

SOX (The Sarbanes Oxley Act)

After the financial scandals of Enron and WorldCom, the U.S. Congress passed the Sarbanes Oxley Act (SOX). This law requires senior corporate executives to certify — with personal liability — that their company's financial statements are accurate.

How would senior executives — including those who are not accountants — know their company's financial statements are accurate? One answer to this question is requiring checking and rechecking of data and calculations. Not only are the numbers audited for accuracy, but also the control processes: Who performed that calculation? Who verified it and documented their verification? Who verified the verification process?

What does this have to do with accruals? Expense accruals feed financial statements, so the process of collecting data and calculating accruals must be documented — in detail — and verified. The actual collection of data and calculation of the accrual must be documented and verified. Any deviation from the process must be documented and verified. The auditors might miss specific instances of SOX non-compliance, but you would not want to bet your job on it. Complicated clinical research standard operating procedures (SOPs) invite errors

and FDA sanctions. The same principle applies to expense accruals, so keep your documented accrual models and processes as simple as possible. You can always perform additional checks and calculations when needed, but perform them unofficially, that is, without documenting them as part of your SOX process.

Perspective

Accruals are estimates — more forecasting than accounting.

If your goal is to determine how many grains of sand wash onto Waikiki beach every month, you can hire a vast army of sand counters to count every grain. Alternatively, you can ask a geologist to create a model that will generate reasonable estimates.

When it comes to accruals, many study sponsors do the equivalent of counting grains of sand. They contact 20 different service providers — and even more sites — every month to provide metrics. They build complex accrual models that call for multiple inputs that require many hours to collect and many more hours to process. Be a geologist, not a sand counter.

The principle of garbage-in-garbage-out can come into play. In a real-life example, a well-known CRO provided "metrics" for a year to a study sponsor and then admitted they were just guessing at a lot of them. When you force a site or service provider to do something impractical, do not expect excellent results.

The solution is keeping perspective. Avoid excess precision, in other words, precision that does not justify the burdensome means to achieve it. Use the 80/20 rule. Do not create sophisticated accrual models that look great on paper but generate results that are not worth the effort or are even worthless.

If your company's leadership is reluctant to adopt methods of estimation that seem risky, demonstrate that they are fit for purpose, i.e., good enough to meet their needs. Run your straight-line and other simple accrual models against two years of actual data to show how close they would have come. If you discover a material difference, then you can create a more complex model.

Auto-Reversing Entries

Auto-reversing entries decouple expenses and invoices. An invoice for January that arrives in February should not count as a February expense.

For example, when an accrued expense is set up as an "auto-reversing entry" for a given month, a corresponding entry reverses that amount on the first day of the following month. So, if you accrue a $1,000 expense in January, the accounting system automatically generates the reverse amount (negative $1,000) on February 1. Then, when the $1,000 invoice for January arrives in February, the January expense is properly in January and the invoice that arrives in February is not counted as a February expense since the invoice offsets the negative amount.

What happens if your estimates turn out to be incorrect? Suppose you estimate that Acme CRO performed $1,000 of work in January and you expect the invoice to arrive in February. You accrue the $1,000 expense in January, which auto-reverses on February 1. If the invoice comes in for $800 in February ($200 less than estimate), a negative balance of $200 (-$1,000 auto-reversing entry+ $800 invoice) carries forward and is credited against the expense account. On the other hand, if the invoice is for $1,200, then an additional $200 charge (-$1,000 + $1,200) carries forward and is charged against the account. In the end, the inaccurate accrual is trued up to the invoice amount.

Figure 1 shows what a typical set of entries might look like:

Figure 1. Example of Accounting Summary with Auto-Reversing Entries

Q1 Actual Expenses for Acme CRO

January	$ 1,000
February	$ 1,050
March	$ 1,175
Total Q1	**$ 3,225**

Q1 Ledger Entries for Acme CRO

Date	Description	Amount	Translation
01/31/22	Acme CRO acct entry	$ 1,000	January accrual estimate
02/01/22	Acme CRO acct entry	$ (1,000)	Auto-reversal of January accrual
02/15/22	Acme CRO invoice #1	$ 900	Actual invoice for January work
02/28/22	Acme CRO acct entry	$ 1,150	February accrual estimate
03/01/22	Acme CRO acct entry	$ (1,150)	Auto-reversal of February accrual
03/16/22	Acme CRO invoice #2	$ 1,225	Actual invoice for February work
03/31/22	Acme CRO acct entry	$ 1,100	March accrual estimate
	Q1 Total:	**$ 3,225**	Actual Q1 expenses (April 1 auto-reversing entry not shown)

Using auto-reversing entries may sound like adding an unnecessary level of complexity but, in practice, they are easy to set up, they smooth your financial statements, and they make it easy to track accrual inaccuracies because each month's financial statements show the total accumulated accrual balance. If the auto-reversing entries balance grows too large, you can adjust your accrual models.

In addition, the auto-reversing entry balance provides you a signal at the end of every reporting period to confirm the accuracy of your original accrual. For example, if no off-setting invoice comes in during the period, you will need to: (a) re-accrue the original amount because the invoice is still expected to come at a later date; (b) take the reversal amount as a "credit" because you've determined the original accrual was wrong and the invoice will never come; or (c) adjust the accrual amount to something more precise based on updated information. Auto-reversing entries also reinforce the concept of accrual-basis accounting, assure everyone that inexact estimates will be corrected, and provide for cleaner financial statements that make more sense.

Invoices as Part of the Accruals Process

A common way that many companies generate at least some of their service provider accruals is for the accounting department to ask internal clinical personnel to provide an estimate. An easy (but unreliable) way a clinical manager might obtain an estimate is to simply ask the service provider what it plans to invoice for that month. Invoices, however, can vary widely and may not reflect corresponding activity at all. Common examples of this mismatch are invoices for upfront payments and milestone payments. For instance, if you accrue an upfront payment for $1 million and no work has been performed yet, you will be overstating your expenses by $1 million.

Additionally, it is often challenging for your clinical managers to know whether to factor into their accrual estimates any invoices they have received or may be aware of, which can result in significant inaccuracies. For example, suppose that, at the end of a month, your clinical manager estimates that Acme CRO performed work totaling $100K during the month. Now assume that an invoice for $60K just came in yesterday from Acme CRO associated with this work. If the responsible manager thinks that the $60K invoice has already been entered into your system, he may give an accrual estimate of $40K ($100K total estimated expenses for the month less the $60K invoice). If, on the other hand, the invoice was in fact not entered, the expense accrual would be short by $60K. On the flipside, if the manager ignores the invoice and provides the full $100K accrual, and the invoice was in fact posted, the result would be an over-accrual of $60K.

Because it is often difficult for managers to know the status of invoices and whether to factor them into their accrual estimates, simply remove this determination from their accrual calculations altogether. Managers should simply assume that no invoice has been received or even exists. After receiving an accrual estimate from a manager, accounting personnel can then look up all invoices posted in the system and offset them against accrual estimates, as necessary. It, of course, helps if your service provider invoices clearly state the services covered.

Actual expenses, accrued expenses and invoices more or less track each other, but they are different financial concepts so you cannot entirely rely on one to calculate the others. What you can do is try to understand how they correspond and monitor them for possible problems in your accrual models.

NAAP vs. GAAP

The accounting world prepares income statements and balance sheets based on an official set of guidelines known as Generally Accepted Accounting Principles (GAAP). The accrual concept and auto-reversing entries are covered by GAAP, but not how you *calculate* accruals. The guideline for that is No Accepted Accrual Principles (NAAP). When it comes to accrual methodologies, if it works, do it. For example, if the last month of each quarter usually has higher patient recruitment expenses, feel free to include that tendency in your accrual model.

Use NAAP to your advantage when designing your accrual models and processes by doing the following:

- Determine your company's level of risk tolerance by giving your company's leaders, especially the CFO and CEO, who are responsible for your public financial filings, examples that test the levels of accuracy they prefer, understanding that higher accuracy can increase costs, slow financial reporting, and create its own risks from additional complexity.
- Generate and implement the simplest, most reasonable accrual methodologies for that level of risk tolerance.
- Make sure your company's executives, solution providers and external auditors basically understand your accrual methodologies. Keep them apprised of any problems, changes or updates.

Conclusion

Because the cash coming into and going out of a business often does not match the underlying activity, accrual accounting can be much more accurate than cash accounting. It is thus required under GAAP. Implementing an accruals process for clinical trials can be very challenging. Always keep in mind seven concepts: accrual vs. cash accounting, simplicity

and practicality, SOX, perspective, auto-reversing entries, invoices (and where they fit into the accrual process), and NAAP.

Reference

1. "Financial Accruals for Clinical Trials – A Primer," Christopher Chan, Journal of Clinical Research Best Practices," September 2013, https://www.magiworld.org/resources/journal/1435_Accruals.pdf

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