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"Happy Trials to You"

# Is Your Site Financially Healthy? By Ari Axelrod

Every business owner wants his or her enterprise to thrive and endure. The owners of clinical research sites are no different. But how can site owners, particularly of sites that have grown beyond small add-ons to their medical practices, evaluate their research site's long-term viability?

To be sustainable over the long-term, your site must generate the financial resources to remain competitive. The cash flow produced by the site must be sufficient to make investments in people and technology, grow in line with its competitors, service its debt, and make cash distributions to its owners commensurate with the capital they have provided and the risk they have borne. In other words, for long-term viability, a site must generate an attractive *return on invested capital*.

Few site owners pay adequate attention (or even know about) this simple yet powerful metric. This is not surprising, given that most site owners are medical professionals with limited training in corporate finance. But return on invested capital is one of the most important, perhaps the most important, measure of the underlying health of the business, an indicator of whether the site can continue to grow, and a scorecard for the managers who lead it.

How is return on invested capital measured and monitored? What benchmarks can we use? How can we determine whether the site generates value for its owners or is being subsidized by them? And what practical insights can we derive from analyzing the returns more deeply? To answer these questions, let's first calculate your site's return on invested capital (ROIC):

$$ROIC = \frac{Net \ Operating \ Income}{Invested \ Capital}$$

In this equation, the numerator is a proxy for cash flow generated by the business after accounting for all expenses required to run it. It is important to include a fair estimate of the cost of the time the owners spend running the business, which typically is not included in the company's financials. Estimating time is a simple matter of keeping a diary for a few weeks. Estimating the effective rate is more complicated, but, as a rough approximation, assume \$120-150/hour.

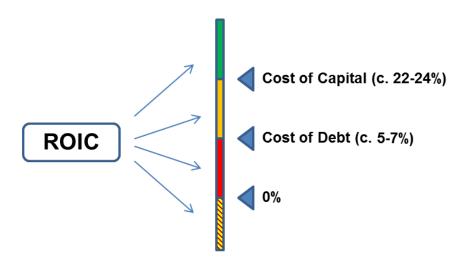
The denominator reflects the cumulative amount of capital tied up in the business: facilities, equipment, working capital (e.g., cash and receivables less payables), etc. It can be calculated directly from the asset side of the company's balance sheet. However, in practice, it is usually more convenient to calculate it by summing up the company's equity and debt (excluding non-interest-bearing liabilities, such as accounts payable).

The primary advantage of ROIC over other profitability metrics is that it reflects the inherent income-generating power of the site's assets and does not depend on how these assets are financed, i.e., how much debt the site has. As such, it can be compared with other companies in the industry, even if they deploy substantially different amounts of debt.

ROIC is easy to calculate based on commonly available accounting reports. Consider the following example (all numbers in thousands) that lead to ROIC =223/1,939 = 11.5%:

Income Statement		<b>Balance Sheet</b>	
Total Revenue	3,377	ASSETS	
Patients' Stipends and Transportation	(274)	Current Assets	1,105
Advertising and Recruiting	(183)	Property and Equipment	855
Employees and Contractors	(2,323)	TOTAL ASSETS	1,960
Operations, G&A	(285)		
Operating Income	313	LIABILITIES & EQUITY	
Depreciation	(57)	Accounts Payable	21
Interest Expense	(33)	Short-term Debt	18
Income before tax	223	Total Current Liabilities	39
Tax Expense	(56)	Long-Term Debt	500
Net Income	167	Owner's Equity	1,421
		TOTAL LIABILITIES & EQUITY	1,960
		Short-Term Debt	18
Operating Income	313	Long-Term Debt	500
Estimated Cost of Unaccounted Owner's Time	(90)	Owner's Equity	1,421
Net Operating Income	223	Invested Capital	1,939

Having calculated the ROIC, we can compare it with three benchmarks: Zero, Cost of Debt, and Cost of Capital, as shown below:



#### Flashing Red Zone: Zero or Below

ROIC below zero is a flashing red stop sign. Your site is financially bleeding! Immediate steps must be taken to identify and address the cause(s) of the problem, be they insufficient enrollment of research patients, bloated cost structure, inefficient processes, or something else. Of course, some of the factors (e.g., delay or suspension of a major research program by a study sponsor) may be temporary. No need to panic, but reevaluation of the site's strategy and operations must be undertaken, and corrective actions, however painful, must be put in place ASAP. Otherwise, the losses might quickly spiral beyond the point of no return.

#### **Red Zone: Positive but Below the Cost of Debt**

ROIC that is positive but below the cost of debt falls in the red "High Alert" zone. Does it make sense to bear the risks of running a site if a higher return can be obtained by simply putting the money currently tied up in the business in a low-risk interest-bearing security like a certificate of deposit? To estimate your site's cost of debt, either use the interest rate the site is currently paying on its debt or, if your site does not have any long-term debt, use the highest rate available on 5- to 10-year certificates of deposit. Bankrate.com is a good source of such data.

For a small business, being in the red zone is not uncommon. It can happen, for example, when the owners of a successful business embark on rapid growth (either organically or by acquisition), borrow the needed capital, and then find that the rosy projections have not quite materialized. What is so dangerous about this situation is that the site's financial reports may, in fact, show accounting profit or even positive cash flow, thus giving the owners a false sense of security. For a while, the site will stay afloat, albeit barely. Yet, if the ROIC remains low and the site continues to grow — which will necessitate further borrowing — the interest payments will soon overwhelm the company's ability to service them. At that point, the loan will most likely get called, turning the once thriving business into a financial disaster.

In most cases, getting out of the red zone requires scaling down and focusing on the most profitable parts of the business. If your site has debt, stop borrowing more, even if means stopping growth, until your site's profitability improves. Among other things, stopping growth will shrink your accounts receivable, freeing up cash to pay off debt.

## Yellow Zone: Above the Cost of Debt but Below the Cost of Capital

The yellow "Proceed with Caution" zone is above the cost of debt, but below the company's cost of capital.

A less precise but probably more credible approach is to look at ROIC generated by companies in the same industry. As a group, established companies in stable industries tend to generate ROIC close to their cost of capital. For publicly traded pharmaceutical companies, ROIC ranges between 18% and 27%. A number in the middle of the range, perhaps 22-23%, should serve well as a reasonable initial benchmark.

In the yellow zone your site is profitable, but it financially underperforms its industry peers. As the owner, you receive a lower return on your investment than owners of similar companies. This is obviously not good, but it is perhaps manageable. After all, you might be attracted to clinical research by non-financial reasons, such as finding new cures, or supporting long-term employees. Nonetheless, there is no way around the fact that your site is underperforming, and the cause of underperformance must be identified and addressed. Have you, perhaps, been lax in increasing study budgets in line with your growing costs? Could it be that you are failing to get reimbursed for some pass-through items? Are your study coordinators motivated and efficient, or have they become complacent?

The real danger of being in the yellow zone is that the owners might have great difficulty in realizing the need to take corrective action. Publicly traded companies have an important indicator: their share price. If the share price falls too low, the business will become a takeover target, and few boards and CEOs look forward to that experience. However, most research sites are privately held, so there is no share price to serve as an early warning signal, and there is no risk of hostile takeover. As a result, a privately owned site can operate in the yellow zone for a very long time, gradually slipping from the upper to the lower boundary of the zone. This slide often happens when the founding owner(s) become

less vigilant or even become willing to accept sub-par earnings in the perceived spirit of loyalty to the business and its long-term employees.

In any case, a business unable to generate returns commensurate with its cost of capital destroys value, i.e., reduces the value of the business to the current and potential future owners. The day of reckoning might come in many ways: changes in the research environment might call for additional investment that a weakened business cannot support; the need to attract expensive new talent (e.g., for digital marketing) that the site will not be able to afford, or, commonly, a much lower than expected valuation when the time comes to sell the site.

### Green Zone: Above the Cost of Capital

If your site's ROIC is above the Cost of Capital, congratulations! You are in the green "Go" zone. Your site is financially healthy. Its economic foundation is sound. With well-considered growth, you are on the right track to enhancing the value of your clinical research business.

#### Conclusion

A clinical research site, like any other business, must generate enough profits to accomplish the owner's objectives, which, at minimum, means sustaining the business as a viable enterprise. ROIC is a convenient and valuable measure of the financial health of your clinical research business. Keep a close eye on the financial, operational and environmental drivers of ROIC, and take immediate and effective action when problems emerge.

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