

The Vendor Tango –

Four Traits to Help You Choose Your EDC/eClinical Partner Wisely

By Timothy Pratt, PhD

You're in a strong, growing company. Your new drug or device is likely to make a big impact in the market, and you need an EDC/eClinical partner to help you get it there. Who should you choose? Who is the right dance partner for your organization? There are a lot of companies in the EDC/eClinical space, most offering a product that looks attractive. It certainly seemed as if there were dozens of new players at the 2007 DIA meeting in Atlanta – a fact that did not escape the attention and concern of others in the industry.¹ It may well be that the Health Industry Insights research results published in 2007 indicating that EDC/eClinical technologies were poised for double digit adoption growth (from 30% of all trials during 2005 to over 75% in 2010)^{2,3} are driving both sponsor interest and entrepreneurial vendor activity. The standing room only EDC sessions at the SCDM conference in September 2007 reinforced that such a move is underway.

This article will *not* deal with the questions of which EDC feature or product is more appropriate for particular circumstances. The focus will not be on the product as such – after all, if your blockbuster drug costs between \$800 million⁴ and \$1.7 billion⁵ to get to the market and every week it's not there represents between \$2 million and \$200 million in lost revenue,⁶ isn't it far more important to you that the vendor is stable and will help you get there? So, this article will deal with the much more fundamental issue of corporate vendor stability. Even if you're not developing the next \$10 million a day drug, the success of your product – and the future of your company and job – can and does depend on selecting the right technology partner. Because no matter how good you are, it takes two to tango, and beauty certainly can be only skin deep.

Favorable Characteristics

Financial stability. You'd probably be shocked to learn that in my experience on the vendor side, fewer than 15% of all customers ever ask about our financials – even the very large customers, of whom we have more than a few. Is this unique? No. In various inquiries and interviews conducted in researching this article, I found similar rates of 10% to 15%. In speaking with sponsors and CROs at recent conferences about financial stability, it became obvious that the idea had never occurred to most. But the issue of financial stability is both important and problematic.

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Why problematic? At a very fundamental level, the overwhelming majority of EDC/eClinical vendors are privately held companies. As such, they do not have to – and in most cases do not – talk about their profitability or financial condition. The few publicly traded companies are required by law to file financial updates providing details on income, cash-flow, balance sheets, expenses, strategic directions, threats, and all sorts of things that have to be right or someone may be going to prison when the SEC investigates. Of the well known publicly traded companies, the minority are profitable and the others are losing money consistently and have done so for quarter after quarter for a protracted period of time.

That alone should cause major concern in the vendor selection process. If expenses consistently are more than income, sooner or later the business will shut down or other major disruptions will occur. If your prospective vendor is publicly traded, finding information on their financial state is very easy via the Internet and should be a fundamental element for review.

What about the private companies? It's very simple: ask. Some people you can trust and some you can't, but you can solve that problem by asking for audited financials and/or taking a financial person along with you for the vendor audit. (You are doing an audit, right?) If you don't have a financial auditor in-house, then take a consultant with you. If the vendor responds, as some have been known to do, with something like, "We're a private company, we don't have to disclose that," then run away, as you have your answer.

Also, watch out for companies that are unduly reliant on one or two customers for a large chunk of their revenue; if something happens in that relationship, you'll suffer too as the vendor undergoes major corporate stress.



Personnel Stability. If your vendor is having major turnover, there's a problem. Sponsors have long been aware of this issue with CROs and make appropriate enquiries to assess it. In technology companies, due to the specialized nature of the work, staff turnover can be extremely difficult to cope with and still provide stable service – again, ask, audit, inquire!

Beyond turnover, if your prospective vendor has been engaging in layoffs or acquisitions, beware. Layoffs, while often a personal disaster for the affected, have a long-lasting negative effect on morale for those left behind. This can and does have an impact on service delivery, motivation, and general performance. On the other hand, acquisitions often involve both major disruptions in service provision, as the acquirer must integrate the acquired into the company (technology and people). In addition, the acquired company's staff may not have wanted to be acquired and may be motivationally challenged as a result.

Company Size. Common business sense tells us that the smaller the company, the more hats each individual wears, and therefore each person has less time to apply to any given element of a study – let's hope it isn't critical to your project. Also, on a more morbid note, but no less important, the vulnerability to major service disruptions due to resignations, family issues, illness, death, etc., is substantially higher. If a 10 to 15 person company sends four people to a conference, which is fairly normal, and the plane crashes (somewhat abnormal but not out of the realm of possibilities), that loss of up to 40% of the company's personnel will have far more impact than the same loss in a company of 50 to 200 people. A less dramatic example of Influenza sweeping through the office and shifting your timelines four weeks is more probable, but almost as problematic.

Company Experience. This is a double-edged sword. If the company under consideration is new to the space (less than five years old), then they have an awful lot of learning to do before you want to risk an important study with them. EDC/eClinical is not as easy as it looks. In a former role at a sponsor company, I chose to try and develop my own system. We hired three IT guys, had \$20 million to spend, and very quickly realized that it was much tougher than it appeared. We finally chose a commercial offering – and later found out another division at that sponsor had spent approximately \$90 million over six years trying to develop a system and had given up.

The other edge of the sword, though, is if the vendor is experienced but their revenues and personnel numbers are low and their market presence is poor – why is that the case? They may fail to deliver well and on time/on budget and have a really

poor repeat business rate (indicative of poor postsales service). Your mission here is to seek out previous customers, but not just the ones the vendor will let you speak to. If the vendor provides you with a list of 10 to 20 people and says, "Call whomever you like," this is a very good sign. If they provide only two or three names and ask you to wait until they make sure it's ok to talk with them, draw your own conclusions. In any case: Ask for a list of all their customers, make some enquiries of your own, and talk to people off the record so that they feel comfortable telling you the unsanitized version of their experience.

Future Partners

Selecting the right EDC/eClinical vendor involves much more than just product functionality and regulatory compliance. Evaluating corporate characteristics such as financial viability, personnel stability, size, and experience is just as important as ensuring there are large stacks of SOPs that are being followed – which, unfortunately, is the focus of many audits.

Corporate vendor characteristics are vital to the success of your clinical study, and a poor decision can be a disaster. If the vendor you select collapses during your study, you'll face a series of very difficult challenges, but that's another article.

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