

# Losing Your Vendor –

## Seven Points to Keep In Mind When Facing the Loss of a Trusted EDC/eClinical Vendor That Can Help Ease the Pains

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By Timothy Pratt, PhD

This is the second article in a two part series. The first article, published in March 2008 entitled “The Vendor Tango,” dealt with four important non product characteristics that should be examined carefully when selecting any support partner, especially an eClinical technology provider: These elements were financial stability, company size, company experience, and personnel stability. I encourage you to go online to the *Applied Clinical Trials*’ Web site ([appliedclinicaltrialsonline.findpharma.com](http://appliedclinicaltrialsonline.findpharma.com)) to review that article if you’re not familiar with it.

If the points raised in “The Vendor Tango” are not borne in mind, the sequelae can be extreme and pose a serious threat to the successful completion of your research. Poor vendor selection can yield results that range from poor performance, inefficiencies, and increased cost through to total vendor collapse.

This article will look at what can easily become a nightmare scenario of vendor collapse during the course of your clinical study. It’s also broadly applicable in the event of a major service disruption or acquisition, where a change in vendors needs to take place. This topic is germane and important to all consumers of eClinical technologies and could easily fill many pages of this journal and not adequately cover everything – so this article will necessarily be a synopsis of the most salient points. Buckle in because it’s going to be a rough ride.

### The Scenario

You’re in the middle of your study; it’s an approval/pivotal study (although during a post-market study intangible effects can be even more far reaching and damaging) and all of a sudden your EDC/eClinical vendor collapses. You panic – and that’s okay, you probably should. The future of your company, your job, your reputation, customer relationships, and more all depend on getting this product approved on time.

You gather your team quickly and identify potential vendors and select one. Now what? EDC is a commodity, so you’ll just be able to switch over, right? Not so fast – you’re about to find out that you will face special challenges, not least of which is the realization that EDC/eClinical is not a commodity and it doesn’t “plug and play.”

Think about it: You’re about to take three to six months of development time – and sometimes years of an ongoing relationship that you enjoyed with your failed vendor – and attempt to compress that into as short a time frame as humanly possible with a company you’ve probably never worked with before.

Communication will be hard. Synergies and understandings will not have had time to develop since people have not yet formed productive relationships. Your team, perhaps even the whole department, is stressed and frustrated. The usual data cleaning activities at study closeout haven’t been performed, the data quality is unknown, and senior management is worried.

These are all special challenges that weren’t present the first time around. So, let’s examine some of those challenges and outline strategies and tactics to mitigate risk and set appropriate expectations.

### Issues and Expectations

**You’ll be separated by a (un)common language.** The terminology you’ve been used to using with your vendor may not be the same as your new vendor. A good example is where the previous vendor referred to an automatic “edit check” as a “query” and the new vendor thinks a query is something that a data manager or monitor issues manually within the system. This simple lack of understanding can cause frustration and delays, especially if the new vendor bids for one thing when you meant another. And there will be many examples like this, so consider developing a printed glossary of terms.

Given the difficulties in common points of reference, it is also even more important than usual that a very detailed and robust User Requirements Specification is constructed. In this instance



do not assume that your new vendor knows (or should know) precisely what you want. You must be as explicit as possible in elaborating exactly what you want and need or you'll be almost guaranteed to get something that isn't, and that will take time and money to fix.

**Processes vary from company to company.** Your new vendor, if you've selected them correctly, has a robust set of processes in place to deliver a good product and service. Trouble is, you've been dealing with your old vendor for so long, sometimes for years, and their processes were different: For example, there will be a lot of change control going on during the changeover, and process mismatch is almost guaranteed.

If you want a speedy and quality job from your new EDC/eClinical vendor, don't attempt to impose on them wholesale process changes in the middle of this project. Just because the processes aren't what you're used to doesn't mean they're wrong or poor. It will take an expert to assess the new vendor's processes effectively, though – more on that later.

**EDC is not a commodity.** EDC and eClinical systems are, by their nature, proprietary. That means they're unique. To expect that your new vendor can or should make a system exactly like the one you had before is unrealistic. There may be fundamental technology vector restraints that make replication either near impossible or highly burdensome, time consuming, and costly.

**It always takes longer and costs more than you think.** This one really hurts – you've already paid for a system after all. To get a new one in place will be at least as expensive and possibly much more, especially if a high degree of commonality is sought with the failed system (see point two: Processes vary from company to company). In addition, if your new vendor is telling you they can do everything in a few weeks, find yourself a different vendor that is prepared to be honest. The temptation, when frustrated and desperate, is to go with the vendor that tells you what makes you feel good, but it's at the risk of significant pain later on.

Switching over to a new system is not easy. Developing an understanding of all the fine nuances of the study and its intent is time consuming. Rushing things inappropriately will cause you to have quality issues.

**Data conversion is not easy.** Actually converting the data is not so hard, but what about all the stuff that makes it meaningful? Table formats, structures, form status, etc.? If you're unlucky enough to just have in your possession a dataset from your failed

vendor, then to expect your new vendor to recreate missing elements (like audit trails, etc.) means you should be aware that the burden, costs, and time required will be significant. Just providing a data dictionary won't be enough, but it helps.

It's easy to make a dataset output mirror the data dictionary, but if you need the structure, for example, to take advantage of SAS programming you've already got in place, that is a lengthy and problematic process. You may want to consider rewriting the SAS programming to allow your new vendor to deploy the new systems as fast as possible.

In addition, if the dataset is relatively "dirty" with many missing and odd values, you'll need to have a plan as to what to do about that.

**Ensure team continuity (and have the best people on the project).** If your study has been ongoing for a while when this problem hits you, chances are the team has changed somewhat. It is going to be very important to have someone on the team that was there at the project's inception and who understands all the subtleties of why things are the way they are and ideally has very good knowledge of the prior system.

You're also going to be under the gun to resurrect your study ASAP and that's a job for your best, most senior personnel. One critical factor here is applying a pithy saying I like: "Beginners need rules because they don't know any better, experts need rules to know when to break them." The point is, an expert will know what is critical in the process and what few corners can be safely cut without compromising quality. Beginners do not.

You should also ensure your vendor is using their most experienced personnel, too. Steer clear of vendors who can only provide technical expertise. The smartest geek or nonclinical project manager in the world can't compete in this instance with someone who actually has clinical experience. As a vendor selection criterion, they should have done this type of rescue work on at least five occasions.

**Don't forget your sites.** Ultimately, all clinical trials succeed or fail based on site motivation and engagement. Hopefully your sites have been eager and engaged, and you'll need to very proactively ensure they stay that way, especially now. Here's how:

- **Training:** Ensure they are all very well trained on the new system. Consider a special investigator/research coordinator meeting to supplement other activities like

Webcasts, online interactive training, and printed materials. Personally visit the most critical sites with vendor personnel if necessary.

- **Communicate:** If, as is common, the new vendor finds that there are holes in the data or that edit checks haven't been working as planned and you need that data, the sites are suddenly going to be presented with a high burden of work in one fell swoop. Make sure they know it's coming and consider ex gratia payments for the extra burden of work required to go back and clean up forms they thought were complete and closed.
- **Use your key opinion leaders/steering committee:** Have the respected physicians who helped develop the study communicate via written letter and/or speak at the special investigator/research coordinator meeting about why continuing the research is so important. They should highlight the new advances in therapy that may result – these individuals' opinions can be highly motivational for the sites.

## **Moving On**

As mentioned, the list of special challenges, issues, and (in) appropriate expectations that need to be dealt with in the event of an EDC vendor collapse are legion and exceed the limitations of this article. What has been listed are a few of the most critical points with some simple examples. Thinking through the points in depth will yield many more examples, which will provide you with more guidance on making the best of a difficult circumstance.

To sum up the situation is deceptively easy: Communicate, ensure understanding, don't expect the impossible, and take care of your sites. Good luck!

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