IN VIVO
CITELINE COMMERCIAL

18 Jul 2022 | **Opinion**

A Delicate Balancing Act: Juggling Multiple Vendors

by Darcy Grabenstein

Costly delays can come from mismanaged clinical trial processes. Consolidation is vital when managing multiple vendors, and study sites, to ensure your team does not drop the ball.

“Multitasking is the ability to screw everything up simultaneously.” So says British broadcaster Jeremy Clarkson of *The Grand Tour* fame. While many folks take pride in their ability to multitask, the statistics paint a different picture. The Cleveland Clinic cites one study that found only 2.5% of people can multitask effectively. An article in *Cerebrum*, drawing from numerous studies on multitasking, posits that “multitasking is almost always a misnomer, as the human mind and brain lack the architecture to perform two or more tasks simultaneously.” And the American Psychological Association notes that multitasking "takes a toll on productivity.”

What’s a clinical study team to do?

In order to effectively conduct a clinical trial, multiple sites and multiple vendors are a must. The saying “It takes a village” couldn’t be more applicable. Just for the recruitment and enrollment of clinical trial participants alone, numerous vendors come into the mix. That means clinical staff members are tasked with monitoring, managing and measuring the efforts of these various stakeholders.

While it may be tempting to go with, say, a single trial site or a single patient recruitment specialist, reality dictates that, in order to meet randomization goals, multiple vendors will get you over the finish line faster. And, especially with a laser focus on the diversity of trial participants, relying on a single vendor will undoubtedly leave you falling short.

If you’re thinking a contract research organization (CRO) could help manage these multiple players, you’re not alone. But CROs still need to connect the dots between digital ad agencies and landing pages, between landing pages and prescreeners, between prescreener form captures

and potential participants, between potential participants and trial sites, between trial sites and sponsors. The list goes on.

What do the regulations say? An article published by the Society for Clinical Data Management refers to the US Food and Drug Administration's (FDA) Title 21 CFR Part 312 Responsibilities of Sponsors and Investigators that requires official transfer obligations to a CRO. CROs should, therefore, expect sponsors' oversight and be prepared to perform vendor oversight for subcontractors to others.

However, regulation and guidance are clear that "Ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor." Sponsors must manage vendors and the vendors of vendors to ensure "quality, integrity, and reliability." And in the EU, ICH E6(R2) (section 5.2) allows for the transfer of any or all trial-related duties to a CRO, with the caveat that the sponsor is ultimately responsible for the quality and integrity of the clinical trial. In short, there's no passing the proverbial buck here.

Trial Recruitment Challenges

Let's face it. Clinical trial teams are overworked and understaffed. Hence the need to outsource key tasks to vendors. In many cases, the teams are so short-staffed that they have trouble keeping up with all their vendors. It's a vicious cycle.

What's up with that?

Several factors compound the difficulty of recruiting and enrolling patients for clinical trials. Certain conditions, such as rare diseases, are obviously harder to recruit for because the potential pool of participants is smaller than average.

Geography can pose a problem for both sponsors and potential participants. This is especially true for rural areas, which often are geographically isolated and lack the level of public transportation available in urban centers. Study sites are usually located at a considerable distance from rural areas, making patients reluctant to commit to traveling and taking time off work — not to mention the associated costs — in order to participate in trials.

Communication remains a huge stumbling block for site staff. Even when they receive information on potential participants, they may not have the bandwidth to follow up on these leads for days, weeks, or longer. Some patients fall through the cracks because they never hear back, which brings us to yet another problem: a lack of trust in the specific sponsor and the pharmaceutical industry as a whole.

The Snowball Effect

Roadblocks such as those cited above can lead to costly delays. Trial slowdowns have become

more the rule than the exception. It's estimated that 85% of all clinical trials will experience delays, with a whopping 94% delayed by over a month. The monetary impact is real, with delays costing sponsors $600,000 to $8m daily.

Say what?

Delays impact not only sponsors but all partners involved in the research process. Smaller companies do not have the financial cushion enjoyed by large trial sponsors and are dependent upon the income generated by their involvement in the research. Trial delays can wreak havoc on their budgets.

Of course, trial delays negatively impact the patients themselves. Depending on the stage of their illness, patients may be in a race against time to find a treatment or cure.

Consolidation Is Key

The key to developing a flexible, cohesive patient engagement and recruitment ecosystem is to make the process more manageable by consolidating workflows into one system. With a single source to manage your vendors/partners, you can spend more time on the actual research and less time on tasks filed under "necessary evils."

When considering a partner or solution to help take the pain out of patient recruitment and enrolment, keep in mind the following features, depending on your organization's unique needs:

- Conducts due diligence by vetting all vendors/partners/subcontractors
- Stores and shares IRB-approved assets
- Reveals pre-set fees up front (no surprises)
- Uses prescreeners to avoid screen fails and delays
- Streamlines handoff of patient referrals to trial sites
- Automates follow-up with patients to minimize manual effort
- Provides continuous communication to patients, vendors and partners
- Offers seamless payment to vendors

Unless you're planning on running away to join the circus, leave the juggling to the professionals. Otherwise, you'll likely end up dropping the ball.

Darcy Grabenstein (darcy.grabenstein@informa.com) is senior manager of content strategy at Citeline Connect, the only end-to-end platform for clinical trial education, recruitment and enrolment.