

Reconsidering Third-Party Companies for Subject Enrollment

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Central call centers can relieve sites of tedious scheduling and record keeping, freeing them to focus on physical exams and other core tasks.

Your study seemed so promising. Your recruitment marketing was compelling and cutting-edge. Your toll-free number was swamped with callers. Yet you still haven't enrolled enough qualified subjects. What's a trial site to do?

Unfortunately, this scenario is all too common in today's clinical trial environment. It's a given that patient enrollment and retention are two of the most important components of the recruitment process, but they can also be the least effective and most costly.

Even though the number of trials is increasing, the patient drop-out rate remains an alarming 40%. Most study coordinators¹—a full 70%—continue to manage their own patient enrollment programs,² often to the detriment of efficiency and strong trial outcomes. If competent third-party companies can provide such services in an efficient, affordable manner, why, then, are less than a third of clinical research outfits using them?

One of the biggest culprits in this scenario of failure is leaving the initial screening responsibility with the sites, especially if advertising is employed. The sites more than frequently cannot handle referrals in a timely fashion. Consequently, back logs build up and significant numbers of participant prospects are lost. In addition, the sponsor has no control over the database of ineligible respondents—which could be used (if respondent consent is acquired) in future trial recruiting programs—because sites are notorious for not providing timely and accurate feedback.



A simple fix for this important part of the problem is utilizing a central call center to do the initial screening. A great many of the initial screening questions can be administered over the phone, leaving blood work and physical examinations to the sites. And the call center can actually schedule appointments for examinations by the nearest site for callers who pass the initial screening. This sends only qualified prospects to the sites and relieves them of the headache of schedule record keeping.

But to many, outsourcing this part of the process is an anathema. It should not be.

The litany of typical objections to outsourcing could include: perceived lack of control, potentially improper screening techniques, and questionable credentials of call representatives. These are understandable reservations. After all, we are dealing with serious matters, some of which can concern life and death.

However, there are call centers that specialize in handling and making health care-related calls, and have experience in screening potential trial participants responding to advertising, promotion, and community outreach efforts. In these programs, a single toll-free number is used either in centralized advertising efforts or in efforts created and executed by individual sites.

Transparency in real time

Using common toll-free numbers results in a central database in which an up-to-date picture is available at all times that details calls received by media, numbers of referrals to individual sites, the resolution of referrals to sites, numbers of randomized patients, and reasons for failure to randomize, among others. Study coordinators end up having one central source of data that provides a complete picture.

Call centers that have recruiting experience do not hire minimum-wage communicators. They pay premium wages and typically use people with health care backgrounds who can efficiently administer applicable inclusion/exclusion questionnaires over the

phone. Some use health care professionals—registered nurses, pharmacists, nurse practitioners, physicians' assistants, and medical technicians.

These call centers also have sophisticated and secure data systems that collect, store, refresh, mine, and report. And, they are completely conversant and fully compliant with HIPAA and Part 11 regulations.

Daily reporting of call volumes and referral rates provide the sponsoring company with more than a measure of control. Report content and frequency can be structured to client requirements. With the above knowledge in hand, a site visit to one or more call centers that put management personnel through their paces should allay the litany of fears.

The preliminary screening and the setting of the first site appointment is a hassle for most sites. What many people fail to realize is that the time and expertise needed to effectively obtain appropriately screened subjects often represents wasted energy and resources that would be better spent managing the trials themselves. Several publications, including CenterWatch, have suggested that sluggish enrollment represents one of the primary causes of trial delays. Yet too many trial sites have been slow to explore the option of outsourcing the job to a company that can sign up suitable candidates promptly and efficiently.

Responses and referrals can be accurately tracked, altering appointment schedules can be easily done, and questions can be answered quickly. Such a centralized screening and appointment setting process can reduce the no-show rate by as much as 50 percent.

A recent survey conducted among physician offices indicated that the barriers to introducing centralized screening and scheduling to sites might not be as thick as one might imagine. The purpose of the survey was to determine what, if any, Internet access capabilities these offices have, and whether or not they would like to have a centralized call center make screening appointments for them for potential subjects who have passed a preliminary phone screen. The survey was conducted via telephone. Personnel responded to the following questions:

- Does your site have an Internet connection?
- Do you have access to the Internet?
- Do you allow an outside company to make appointments?
- Would you prefer to have access to a secure Web site to obtain appointment information?

The survey sample size was 100 sites involved in a large type II diabetes trial. The survey found that 92% of respondents said they have access to the Internet, and 65% said they would rather get referrals through a Web site. Another 70% said they would prefer not to have to deal with appointments.³

These views suggest to us that, properly positioned, a centralized call center would not be too hard a sale to most sites, especially if the sponsor were to take a strong position that stressed the benefits to the sites.

References

1. K. Getz, CenterWatch Review of 1999–2001.
2. K. Getz, CenterWatch surveys of investigator sites, 2001.
3. Alliance Survey, Healthcare, Inc., 2002.

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Questions to Ask in Evaluating a Third-Party Call Center

Having the answers to the following questions will help you identify which call centers are best suited to execute centralized preliminary phone screening:

1. How many clinical trial recruiting programs has the call center completed?
2. Can the call center provide a list of the audiences and disease states?
3. Can the call center provide a perspective on the size of these trials in terms of numbers of participants sought, number of sites involved, size of media budgets and media choices, and urgency of the sponsor in enrolling participants?
4. How many inbound stations does the call center have? What is the capacity of the stations that can be assigned to this program? How would you handle spikes in volume due to media response?
5. Does the call center have a "switch," also known as an Automatic Call Distributor, or ACD? (This is critical; it allows calls to flow evenly to call representatives and enables call tracking and reporting so that you can control costs by measuring productivity, service levels, and average call length for each representative.)
6. How familiar is the call center with using the Internet to recruit participants?
7. Have you executed programs where your call center has scheduled the first appointment at the appropriate site for qualified potential subjects?
8. What kind of back-up systems does the call center have for power, light, computer hardware, and phone systems? How long would it take to be back in operation in the event of a fire, flood, or other disaster?
9. What knowledge and/or medical background does the call representatives have related to essential information about inclusion/exclusion questionnaires, research sites, protocols, study coordinators, investigators, CROs, CRAs, IRBs, MedWatch, etc?
10. Do your project managers know how to flow the most useful information to call representatives in a timely manner?
11. Is every single call floor station computerized?
12. What will your hours of operation be? What do you consider to be acceptable service levels?
13. Do you have a staff of computer programmers on hand at all times for emergencies and to help adjust the call guides, appointment schedules, enrollment tracking and site information database as necessary?
14. Can you give us an example of your previous performance?
15. Do you currently have a patient recruiting program in operation that we could call into so that we can take your company for a "test drive"?