Top Ten Myths in Clinical Trial Enrollment and Retention

Scott Connor, VP Marketing, Acurian

The efficiency with which investigator sites enroll patients is still one of the most critical drivers of timely trial completion. However, it is no longer realistic to expect sites to enroll their patient quotas using their own databases.

Complex trial designs have put a strain on patient availability. Competition for patients in the same therapeutic area has grown fierce. CRO alliances have put a stranglehold on clinical teams who need specialty recruitment and retention services.

In the midst of this changing paradigm, it is all too easy for trial sponsors to be distracted by common myths that prevent them from turning enrollment challenges into opportunities. Ask yourself these questions: Are you caught up in the belief that your CRO can handle patient enrollment and retention? That your sites will enroll to timely expectations? That more money for advertising equates to more patients for your study? These misconceptions can lead to misfires in both enrollment and retention.

Myth vs Reality

Following are myths and misconceptions from a number of leading industry sponsors, along with the facts to help you to adjust your thinking about patient enrollment and retention strategies.

Myth #1: The CRO we hired is qualified to design and execute a patient recruitment and retention strategy.

CROs are well qualified to conduct most aspects on a clinical study. However, they lack the necessary patient enrollment and retention expertise offered by specialty recruitment providers. Many CROs have built extensive patient recruitment departments to assure sponsors during the bid process that their company is qualified to recruit patients, but these departments have no differentiating capabilities and often outsource enrollment services to third parties. CROs actually benefit when a study falls behind in enrollment. A large percentage of CRO revenue is based on change orders that are issued to extend enrollment or add more sites because enrollment is behind schedule.

Myth #2: We’ve selected the best sites and they will be able to enroll this study.

Despite the industry’s best attempts at recording and categorizing site enrollment performance worldwide, not a single CRO or sponsor has been able to proactively identify
sites that will consistently deliver 100% of their enrollment goal. Why? It is virtually impossible to do so. Too many factors affect site performance, and even the best sites can be horrible underachievers on any given study. No matter how good the site selection process is, the consistent pattern is that only 25% of sites selected will enroll to expectations. Therefore, sponsors will often need to supplement in-practice recruitment with enrollment services that find patients who are not part of the sites’ practices or databases. Enrolling out-of-practice patients is a faster and more cost-effective method than adding more sites and time.

Myth #3: We can enroll all the patients we need using social media.

Social media has created wonderful venues for patients to share experiences and stories about managing and living with a variety of medical conditions. More importantly, social media channels like Facebook have aggregated millions of people who can be targeted by high level demographics such as gender, age, and location. Tapping these online populations has become an important augment to traditional recruitment methods, but by no means can social media contribute all trial participants as study teams hope. Protocol designs and site geographies continue to significantly cut the available trial population, so any single-threaded approach to enrollment will fail for trials requiring significant volume.

Myth #4: Basic text messaging is all we really need as our retention communication strategy.

New retention methods such as text messaging have shown great promise, and the amount of data validating text messaging as a patient communication strategy is growing every year. Therefore, text messaging is important in the new world order of retention. However, communication-based retention programs must accommodate all patients, and 40% of Americans with cell phones do not have or do not use text messaging. You should always consider a retention strategy that provides all study participants and sites with several two-way communication options, including mobile phone text (SMS), email, and landline phone messages.

Myth #5: People in the U.S. are not interested in clinical trials.

The issue is not one of interest. It is one of awareness. For example, direct mail response from people in the U.S. to clinical trial opportunities is actually between two and five times higher than consumer package goods and financial services offers. The problem is that only a small fraction of people know how to find or understand trial opportunities. And while their reasons for participation vary, people routinely show a strong interest in clinical trials once they understand the options. Sponsors can absolutely leverage a high level of interest from U.S. patient populations, but they cannot rely solely on sites’ own patients to fill the trials. This is increasingly the same situation in other developed countries or those with more accessible healthcare options. The key driver in all cases is awareness, both at the site level and within sites’ local communities.

Myth #6: We can enroll our studies by giving sites money to run advertising.

If you can enroll with this strategy, count yourself as one of the lucky few. Purchasing advertising effectively takes industry-specific experience, savvy and skills. Sites are also generally small businesses and don’t have buying clout with local media channels, which is a huge disadvantage in major media markets (big cities). But the cycle of giving sites anywhere from $2,000 to $10,000 to do their own advertising is a hard one to break. In fact, sites often expect advertising dollars as a matter of course, but are not held accountable for results. Some sites use the money well, but most are not equipped to invest it properly. If this strategy truly worked, enrollment would not still be a huge issue for most clinical trials.

Myth #7: Our sites already have processes in place to retain our patients.

To their credit, sites do often try to implement their own processes to help reduce patient attrition. However, it simply isn’t working. Widely published data from the Tufts Center for the Study of Drug Development shows that patient drop-out rates are rising at an alarming rate, and protocols are only getting more demanding for patients. No longer can sponsors rely on a handful of sites to utilize home-grown and inconsistent retention processes to protect their substantial investment in trial participants. Sponsors today have new choices with regard to retention strategies that are based on what patients want and need. Moreover, these choices are removing the retention burden from busy site staff and are providing centralized, metrics-based technologies that bring a critical level of transparency, accountability and actionable data to the table. Sites are best when they focus on patient care. They should not be charged with trying to manage patient retention within
wide ranging study visit schedules and patient preferences. Outsourcing that work to a third-party service improves retention rates and provides insurance against patient loss.

Myth #8: Adding more sites is a cost-effective patient enrollment solution.

Not likely. Think about the logic of site selection: Sponsors or CROs select sites over others based on sites' ability to enroll the targeted population. Therefore, when these top-rated sites fall short on their enrollment numbers, there is little chance that adding second or third tier sites will match or do better than those original sites. Moreover, it takes months and expense (e.g. $20,000 to $75,000) for the study team or CRO to locate, evaluate and initiate each new site. Detailed analyses done by clinical trial cost-estimating software companies like ClearTrial have clearly shown that the cost of adding sites or time (and rarely are these even mutually exclusive) is far more expensive than the costs of services to recruit and enroll out-of-practice patients.

Myth #9: Minorities such as African Americans and Hispanics will not participate in clinical trials.

Many sponsors believe that there is a particular and widespread mistrust of clinical trials in the African-American and Hispanic communities, largely stemming from the much publicized trial misconduct by the U.S. Public Health Service of poor, rural African-Americans in Tuskegee, Alabama from 1932 to 1972. Fortunately, clinical trial design and oversight in the U.S. has changed dramatically since the early 70s. Today, more than ever, patient care and protection is at the forefront of the research industry. And minority participation in trials is increasingly important, with government agencies like the FDA strongly recommending that certain studies have specific and sometimes exclusive minority representation. The good news is that interest in clinical trials from minority populations is not only equitable compared to whites, in many cases it is stronger. For example, recent work by Acurian in recruiting patients for hypertension found that African Americans were two times more responsive to direct mail outreach than whites. Recruitment for other disease states like diabetes, atrial fibrillation, high cholesterol, asthma and hepatitis C were equally robust within minority populations. As with other races interested in trial participation, minorities are looking for potential treatment options, detailed study information, and respect.

Myth #10: Most patient recruitment companies are qualified to handle sensitive patient data and have the appropriate privacy/security measures in place to ensure that sponsors are not at risk.

The majority of patient recruitment service providers are advertising and public relations firms that have decided to re-focus all or part of their business toward the clinical trial industry. While these providers rely heavily on their creative capabilities, it is not uncommon for them to have pieces of software and databases that provide sponsors with certain aspects of enrollment tracking and reporting. However, most of these systems have not been developed to international privacy and security standards, nor have the companies themselves invested in critical technology standards and third-party validation to ensure the protection of patients and sponsors. It is true that patient recruitment companies are not HIPAA-covered entities, but that does not preclude sponsors from ensuring these providers have the proper measures in place to ensure patient privacy and trial data security. It is imperative during the bid and vendor selection process that you ensure all patient recruitment providers give ample proof that they can deliver services with the proper level of patient and data safeguards.

Retain This

How many of these myths have played a role in the execution of your clinical trials? How many have now been busted, or have you at least thinking about the rebuttals you just read? If you found that there were a number of these myths that resonated with you, you are really not alone. Now, you’re no longer being misinformed as well.
About Acurian

Acurian is a leading full-service provider of clinical trial patient enrollment and retention solutions for the life sciences industry. The company increases the enrollment performance of investigator sites worldwide by identifying, contacting, prescreening, and referring people who live in the local community but are unknown to a research site. As a result, trial sponsors complete enrollment without incurring the unexpected expense of adding sites, time, or CRO change orders. Acurian’s investors include Euclid SR Partners, ProQuest Investments, JP Morgan Partners, Flatiron Partners, CDP Capital Technology Ventures, and Merck Capital Ventures.

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