Top 10 Patient Enrollment AND RETENTION MYTHS

Myths can Lead to Misses

Today's trial climate frustrates many clinical study teams. Operations must deliver quality trial data under intense pressures. Larger, longer, and more esoterically designed trials place a strain on patient enrollment and retention. Fact and fiction are blurring in this environment. We've developed a list of common myths, followed by our perspective on reality.

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

It is true that CROs are well-qualified to conduct most aspects of a clinical study. Without question, trial sponsors need CROs in order to process the sheer volume of work. However, CROs absolutely lack the specialized expertise and resources required to expedite enrollment. Despite the very real fact that most major CROs have built extensive patient recruitment departments, they have no differentiating capabilities. In fact, CROs often outsource enrollment services to third parties. CROs actually benefit when a study falls behind in enrollment. It is no surprise to anyone in the clinical services industry that a large percentage of CRO revenue is based on enrollment failure. This revenue comes in the form of change orders issued to extend the enrollment timeline or add more sites. Again, CROs are important resources for advancing clinical research. They just aren't qualified to remove the most important trial obstacle, and in fact they financially benefit from delayed enrollment. If CROs were experts in this arena, they would price patient enrollment on randomized patients, which to date, they have not done.

Myth 2: We've selected the best sites and they will be able to enroll this study using their own patient populations/database.

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 underachievers on any given study. 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 often a faster and more cost-effective method than adding more sites and time.

Myth 3: We can enroll all of 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 many clinical 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. Social media is great, but finding all the patients you need in the cloud is still a long ways off.

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.

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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. This 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, these simply aren't working. Widely published data from the Tufts Center for the Study of Drug Development show 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 this 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 the 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 — for example, $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, such as 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 1970s. 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 with 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, such as 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.

Dismiss the Myths

Excitement over innovative enrollment approaches is growing, for example virtual trial designs, social media, and electronic health records. Pharmaceutical sponsors should take note, but not at the expense of ignoring some fundamental myths that make innovation a moot point.

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