

# Accelerating Patient Recruitment For Medical Device Clinical Trials

by Mark Summers

*New medical devices are being developed in unprecedented numbers and with growing technological complexity. Simultaneously, the regulatory bar is being raised, necessitating increasingly complex clinical trials with ever larger patient populations. Hence, the always challenging task of patient recruitment is being elevated in both scope and difficulty, resulting in many new medical devices suffering from long delays to market entry. A growing number of medical device firms are responding by seeking to accelerate patient enrollment through proactive recruitment of study candidates. This article describes a methodical approach for planning and implementing a patient recruitment strategy and its associated benefits.*

## Introduction

Time is arguably the most valuable resource available to companies developing new medical devices. It is also one of the most controllable and quantifiable, yet most under utilized of all resources. The largest consumer of time is often the clinical trial process, and within that process, patient recruitment is frequently the primary factor holding up project completion. Taking too much time for patient recruitment leads to delays in market launch and losses of revenue, competitive advantage, and, in the case of start-ups with a single new product in development, even entire companies.



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### **Time = Most Valuable Resource**

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Although many factors such as bad protocol design and poor site selection can negatively affect enrollment, most delays are brought on by simply not planning ahead. Therefore, for enrollment to be accelerated, it is not only possible but essential that a well thought out and effectively implemented recruitment program be put in place so the maximum value of time savings can be realized. This is true even for trials of devices in acute care settings where there is little ability to proactively reach out and engage targeted populations of candidate patients.

For the vast majority of medical device clinical trials, patient recruitment goes no farther than routine screening of patients already scheduled for regular clinical office visits at investigative sites. Although screening of these patients is foundational to successfully enrolling a trial, it should not be the only avenue pursued. It is possible to design a recruitment system that will not only lead to better onsite screening of more patients but also will reach out to the population of targeted patients and bring more of them into the sites.

Aside from the intrinsic value of getting to market faster with a new product, the financial returns from an investment in proactive recruitment are often enormous and can be realized almost immediately. For established companies, accelerated recruitment moves the entire market life cycle ahead on the calendar, meaning shorter times to product launch and market establishment as well as larger market share. Start-up companies accrue the added benefit of shortening “cash burn” time. Suffice it to say that a well-executed patient recruitment strategy resulting in faster time to market can easily carry a return of several-fold the initial investment.

#### **Two Ways to Accelerate Enrollment**

- 1. Increase numbers of patients**
- 2. Improve screening process**

There are two ways to accelerate patient enrollment: increase the numbers of patients available for screening at sites, and improve the screening processes within the sites. It should be noted here that maximizing retention of enrolled patients is also crucial for speeding up overall trial completion; however, the focus of this article is on the recruitment process.

What follows is a description of a method for breaking down patient recruitment into four key steps, from which an efficient plan can be developed, implemented, and managed. The resulting plan will not only

make certain that every potential patient candidate at a site is screened but also that an increased flow of pre-screened candidates will be directed to sites. The article will describe how to get started, setting and managing expectations, and deciding whether to use internal resources or to outsource.

## Four Elements of an Effective Patient Recruitment System

For purposes of clarity, the term patient recruitment will be used in this article to describe the entire continuum from identification of patient candidates all the way through to enrollment. Hence, accelerated enrollment will be taken to mean the same thing as accelerated recruitment, since one leads to the other, and one cannot be achieved without the other. Therefore, the goals of a successful patient recruitment system are, quite simply, to locate and engage the greatest number of patient candidates as quickly as possible,

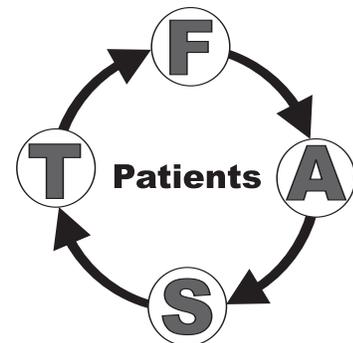


and pre-screen and connect them with study sites where efficient and effective final screening and enrollment takes place.

A good way to construct a proactive patient recruitment system is to divide it into four key elements. The four are:

- **F**inding and engaging patients;
- **A**ssessing or pre-screening them according to inclusion and exclusion criteria contained in the study protocol;
- **S**cheduling them for screening visits at sites; and
- **T**racking them throughout the process to make certain they are not lost in the system and to measure progress.

To help with remembering these, think of the acronym F-A-S-T. Let's look at each of these elements in terms of planning, implementation, and integration within a systematic structure. Thinking of a systematic construct is extremely important, since a system involves the use of predictable and repetitive processes, which make for accurate measurement of performance. A systematic approach also ensures that patient candidates will not slip through the cracks after time and money have been spent identifying them.



**Find → Assess → Schedule → Track**

A great deal of detailed planning and execution are required for each of the four elements. The following paragraphs will provide an overview of each element.

### **F** Finding and Engaging Patients

The population of potential patient candidates can be divided into two groups: known and unknown. Known candidates are those the investigator site is already familiar with by virtue of being a current or past patient. Unknown patients are those with whom the site has no current or previous relationship.

Known patients with a current or new relationship at the site obviously do not need to be found, since they are presently being seen at the site, so they will not be addressed in this section. However, it is essential that each of these who meets the study inclusion criteria is successfully screened, so the assessing,

scheduling, and tracking sections of this article will be relevant to this population.

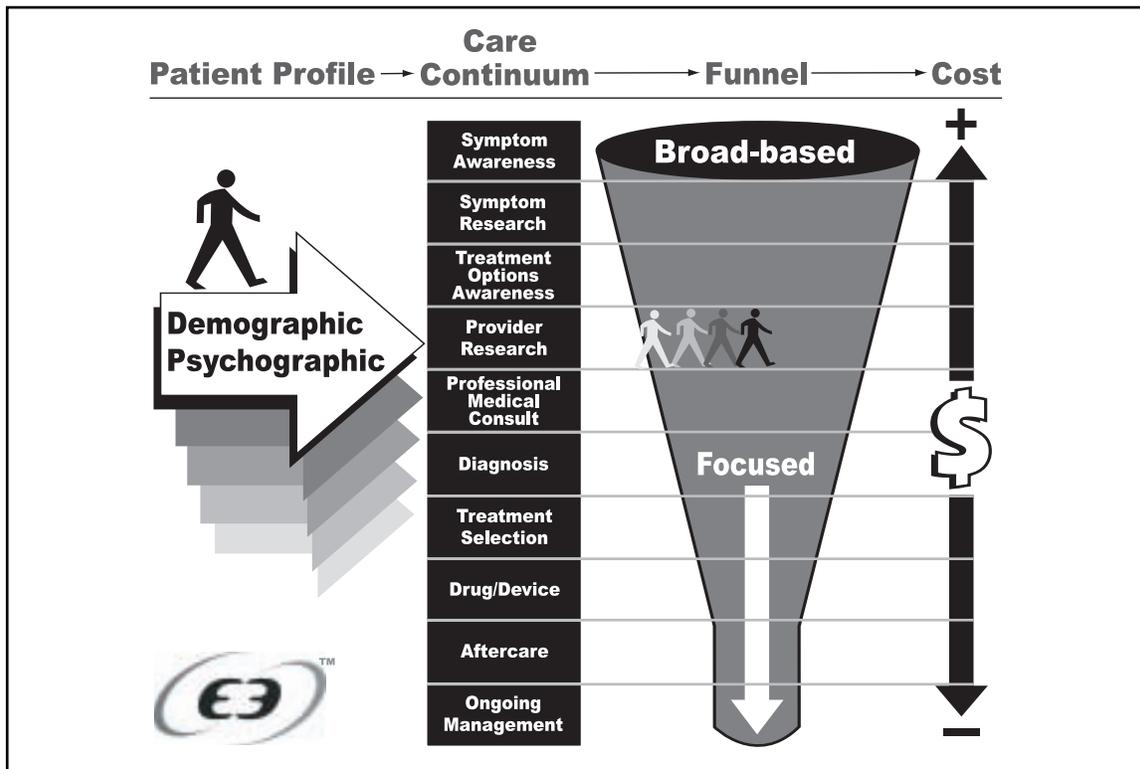
Therefore, this initial step of finding and engaging patients will be focused on those who are either unknown to the site or known to the site but with no current relationship. The first half of this step, finding patients, involves identification of the maximum number of patient candidates around and within sites as quickly and cost-effectively as possible.

## PATIENT CANDIDATES



For unknown patients, start with constructing a patient profile by evaluating basic demographic and psychographic information. This will aid in determining where to locate them and what kind of message will appeal to them. Next, consider the continuum of care. How and by whom are these patients diagnosed? Which clinicians provide primary and specialty care? How do these patients make decisions about choice of therapy and clinician? Is there an established referral pattern between clinicians? Will reimbursement be an issue?

This information indicates where the greatest numbers of patients will be found in the funnel, along with a qualitative analysis of acquisition cost per patient. As a rule of thumb, the more narrowly patients can be identified and targeted within the funnel, the lower the cost per acquired patient candidate. The following diagram illustrates this principle and provides a template that can be customized for a specific product:



Known patients with a past relationship at the site can be uncovered through screening patient records, either manually or electronically using relevant ICD-9 (International Classification of Diseases) diagnostic or CPT (Current Procedural Terminology) billing codes. A brief word here about the legality of patient record screening: it is entirely legal and ethical to do so as long as the screening and subsequent engagement processes are conducted by site personnel with Institutional Review Board (IRB) approval.

If, as is often the case, a significant number of known patient candidates can be identified and accessed within the site's database, a direct mail piece in the form of a letter from the investigator is most

appropriate. The same approach can be used to great success with referring physicians, who are often quite willing to refer their patients for screening in medical device clinical trials, as long as they are not therapeutic competitors with the investigator specialty.

The biggest challenge with patient record screening is that sites often have neither the time nor experience to perform this task properly. Therefore, the key is assisting the physician by doing it for them, through providing the staff and financial resources necessary to complete the task quickly and efficiently. As long as the staff is employed by the physician, either directly or through a contractual relationship, outside management can be provided for that staff person. Identifying patient information is kept confidential until the patient elects to respond by calling for more information or pre-screening.

Once the locations of unknown patient candidates are determined, communication tools for reaching out and engaging them can be created and deployed. Again, the goal is to achieve this as rapidly and cost-effectively as possible. Methods of outreach can vary greatly but will be dictated in large measure by where patients are in the community, within the healthcare system or investigative sites. The most successful outreach will involve use of media tools. These can run the full gamut of online and offline media, including Internet, email, direct mail, print, and broadcast advertising. The demographic and psychographic profiles will provide both media targeting and messaging information. Do these patients use the web? How do they search for information? Which sites do they visit? Which publications do they read? What radio and television stations do they tune into and when? A common perception in the medical device industry is that broadcast media is prohibitively expensive. However, for the right product, a very cost-effective broadcast media plan can be developed and executed that will yield huge numbers of patient candidates. And remember, investments in accelerated patient recruitment yield savings of time to market, often with a several-fold return on investment.

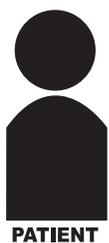
Finding and engaging targeted patients is all about speed, efficiency, and cost-effectiveness. Think of harvesting fruit from a tree. The lowest hanging fruit is always picked first because it is quickest and easiest to reach. Always start with the “lowest hanging” patients and work up from there. Therefore, this usually translates into evaluating and targeting known patient populations first, then unknown patient populations.

# A

## Assessing Patients

Once patients have been engaged, the next step is to assess them for possible inclusion in the trial. The key to success at this juncture is to establish and maintain direct contact with patient candidates until they are both screened and enrolled at the site or drop out of consideration. The best way to accomplish this is to employ an intermediary for all initial patient contacts except those who are known with a current relationship at the site.

Here is how it works: each patient outreach tool contains a highly descriptive call to action, such as telephoning a toll-free number or sending an email response. These inbound contacts can be handled by an intermediary in the form of a contact center. This can be an in-house center or it can be outsourced. The most important thing is that it must be staffed with knowledgeable and professional individuals, because this will be the patient’s first interaction with the sponsor and their trial.



Use of an intermediary accomplishes two things. First, it ensures each patient’s response is handled immediately and in a professional manner. The importance of this cannot be overstated, since the patient’s initial impression will greatly affect their willingness to participate and the speed with which they can be subsequently screened and enrolled. Second, it controls contact with the patient, preventing them from slipping

through the cracks due to their own or the site's unresponsiveness or inability to connect. It is amazing how many potential trial subjects who have been successfully located and engaged never reach the screening stage because of one or both of these factors.

## **S** Scheduling Patients

After successful pre-screening by the intermediary, each patient is positively handed off to the respective site to book a screening appointment. This can be done by three-way conferencing or by booking appointments directly with sites. Whenever possible, this should occur during the very first contact with patients who successfully pass the assessment, or pre-screening stage. This is important since research has demonstrated that patients whose appointments are booked during their first contact are subsequently enrolled at higher rates and with shorter timeframes than those who are not.

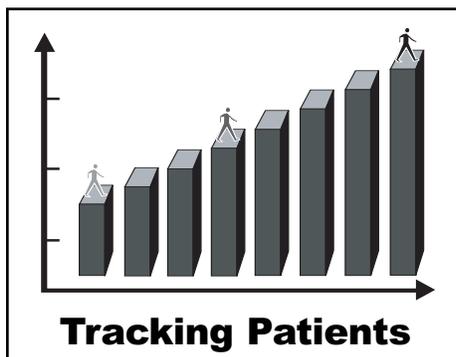
The ultimate goal is accelerated recruitment. Efficient and orderly processing of respondents by knowledgeable staff translates into more enrollees in less time. Use of an intermediary is highly recommended since very few sites have the ability to efficiently do this themselves, despite the belief of many to the contrary.

## **T** Tracking Patients

Tracking patients means staying positively engaged with them all the way from initial engagement through assessment and scheduling to both enrollment and retention as appropriate, or prior drop out due to screening failure. The aim is to always know where the patient is in the system at any given time, as well as the next step and when that step will be completed. Successful tracking requires constant communication and follow-up with patients and sites. Losing track of patients, especially prior to enrollment, will almost certainly mean losing them as potential study participants. That means loss of the investment made to find and engage them in the first place, as well as time and expense to recruit patients to replace them.

Tracking patients sounds simple and, in fact, can be from a systems standpoint. However, paying consistent attention to detail is the ultimate key to tracking success. This means designing an excellent system for tracking patients and executing many details with superb discipline and persistence. It also means putting a central database in place and creating clear tasks and accountabilities for patient communication.

An added objective of tracking patients is gathering metrics for the purpose of measuring recruiting program performance. This information will prove invaluable for fine-tuning program design after launch. Also, a great deal will be learned about your product, competition, and patient and clinician behavior as they interact with your product. This information will be invaluable as you plan for post-regulatory product launch.

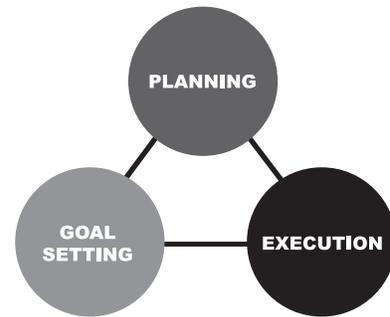


A word about patient privacy: it is extremely important to comply with patient privacy regulations as well as good common sense in this phase. Patients must always opt-in to share their information as well as give their consent to contact them in the future. Privacy policies should be clearly stated, have legal department approval, and be readily available to patients. Experience has shown that a patient recruitment system that engages patients and provides them with real value in a credible way, and in which patients have confidence in how their information is stored and used, will yield opt-in rates nearing one hundred percent.

# Getting Started

Thinking like a marketer is one of the most important principles to master when planning a patient recruitment program. After all, proactive patient recruitment is a form of direct-to-patient marketing; the difference is that a clinical trial is being marketed to patients instead of a product.

There are three important elements to developing and launching an effective direct-to-patient marketing system: planning, goal setting, and execution.



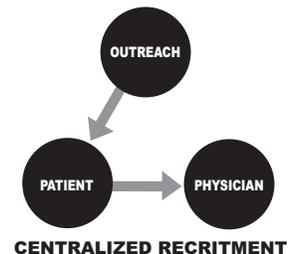
## Planning

Effective planning starts with detailed research and analysis. As mentioned previously, a thorough understanding of the targeted patient population and associated care continuum is essential. This includes in-depth demographic and psychographic breakdowns with the goal of understanding where patients are and which channels will be most effective for reaching them.

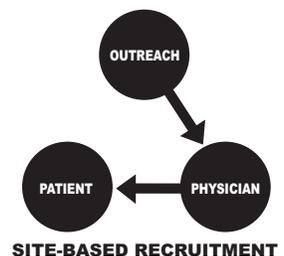
Several other critical success factors should be taken into consideration when planning a patient recruitment initiative. Among the most important of these are: centralized, site-based, or combination strategy, key site characteristics, number of enrolled patients needed, Institutional Review Board characteristics, timeline for completion, availability of reimbursement, and budgetary resources.

## Centralized, Site-based, or Combination Strategy

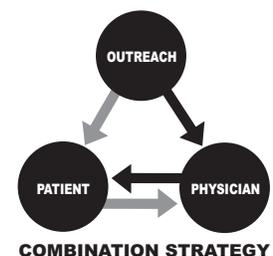
A centralized approach is defined as one wherein a single recruitment strategy is developed and applied through a central management system across all participating sites. Generally speaking, such an approach works best with large populations of patient candidates in chronic disease categories and less restrictive inclusion and exclusion criteria.



A site-based approach is defined as one in which the mix of recruitment tactics is either varied from site to site or is implemented primarily at the site level. This type of approach is ideal when large numbers of patient candidates can be identified through sites, either in their databases of existing patients or through referrals. A site-based strategy is most effective with more complex disease categories or protocol criteria, when referral patterns keep patients away from investigator practices until interventional treatment is needed or for acute conditions with shorter times from diagnosis to treatment.



A combination strategy utilizes elements of both centralized and site-based approaches by targeting patients both inside and outside investigator practices. This is the strategy that will most commonly be employed in accelerating recruitment for medical device trials.



## Key Site Characteristics

The number and location of sites is important to consider when planning for patient recruitment, as is the size of the target population at each site. Also key is whether the site is an academic or private practice, since academic sites can be difficult to work with due to lengthy IRB and administrative review and approval processes, particularly if they have no previous experience with proactive patient recruitment.

Another important site characteristic to consider is patient capacity. Some trials can require several hours of onsite screening prior to qualification and enrollment. Other trials may require large numbers of screened patients to secure the needed numbers for enrollment. Whatever the case, make certain each participating site has the necessary capacity for screening the increased volume of patients generated through an accelerated recruitment system.

### Key Site Characteristics

1. Number of sites
2. Location of sites
3. Size of patient population
4. Academic or private
5. Previous experience
6. Patient capacity
7. Interest and willingness

Another site factor critical to the success of a recruitment initiative is their interest in and willingness to positively engage in a proactive recruitment program. Investigators sometimes have motivations for getting involved with a clinical trial that run counter to a sponsor's goals, such as status as a key opinion leader or publicity. Unwillingness to participate or disinterest in aggressive patient recruitment can preclude their involvement, not necessarily with the trial, but with sponsor-led recruitment initiatives. It is not necessary to work with all sites. In fact, it may not even be advisable. Surveys show that, on average, one third of the sites in a given trial will fail to recruit more than a single patient. The impulse is to believe that providing assistance to poorly performing sites will greatly improve their performance. Following this impulse will most often lead not only to disappointment but also to wasted time and other valuable resources. Patient recruitment should focus on the middle to top performing sites that are willing to engage in an accelerated program.

All of the above characteristics should be taken into consideration during the site selection process, as each will affect the subsequent success of patient recruitment.

## Number of Enrolled Patients Needed

The number of patients needed primarily affects the projected timeline for recruitment and tactical scope. It is not an indicator of whether or not proactive recruiting is needed. Examples abound where patient recruitment languished in the single digits for months, even when only ten or twenty patients were needed. Such cases make accelerating recruitment more important, not less.

## Institutional Review Board (IRB) Characteristics

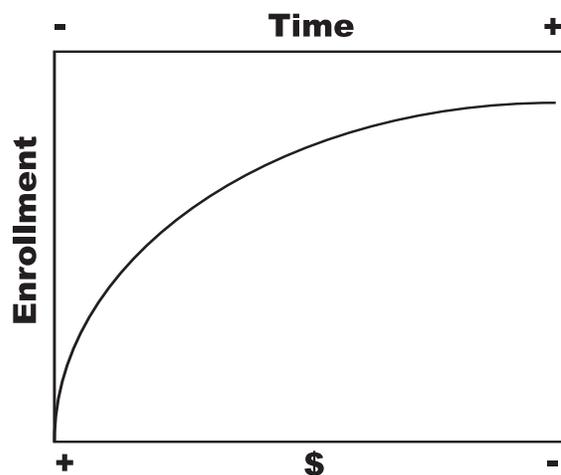
Two factors are important to consider: whether centralized or individual site IRBs will be used, and ease of working with each IRB. Due to the interventional nature of most medical device trials, sites will probably require local IRB approvals. All materials involved with patient recruitment, from print collateral, all advertising and promotional materials, web copy, call center scripts, etc., must be approved in advance by the IRB at each site engaged in patient recruitment. Therefore, characteristics of each IRB such as experience, frequency of meetings, and review and response times must be taken into consideration when deciding which sites to work with on patient recruitment.

## Timeline for Completion

The targeted timeline for patient recruitment is foundational to planning. Not only will it serve as a basis for setting goals and managing expectations, but the desired timeline for completion of patient recruitment will play a large role in budget determination and forecasting return on investment.

## Availability of Reimbursement

The availability or lack of reimbursement will greatly affect patient recruitment, unless the sponsor is prepared to bear all device and procedure related patient costs. It will be important to assess reimbursement for both the device and any associated procedures. If procedural reimbursement can be established but is limited or non-existent for the device and the sponsor expects to sell the device, then the patient's ability to pay will be a linchpin in the recruitment effort and must be factored into targeting and pre-screening. Likewise, if reimbursement will be limited to certain insurance carriers or types of coverage, then this will be an early screening criterion.



Just as with a marketing program, understanding the reimbursement landscape will be critical to patient targeting, engagement, assessment and screening. A thorough evaluation of third party reimbursement and development of a cohesive strategy in the planning stage will preclude unpleasant surprises and delays after the start of a trial.

## Budgetary Resources

To a high degree, spending acts as an accelerator pedal. The truth of this principle will be in direct proportion to the quality of advance planning and program execution. Therefore, somewhat of a chicken and egg relationship exists between budget and timeline, and these two factors combine to form the foundation of return on investment for a patient recruitment initiative. Notwithstanding the foregoing, there will always be a limit to the budget for a clinical trial. Understanding the available resources in advance will in large measure drive the breadth and depth of the tactical game plan.

It is impossible to overstate the overall importance of proper project planning, as the time and money spent on the program will be returned multiple times by a smoothly functioning and successful recruiting system.

## Goal Setting

It is extremely important to set realistic goals and manage subsequent expectations for key stakeholders at both the sponsor and investigative sites. Such factors as time to develop, build, and launch a patient recruitment system, as well as ramp-up time are critical. A systematic patient recruitment initiative is a complex project with many moving parts, and is highly dependent on a wide array of factors both internal and external to the program management and execution teams. Success rests only in part on having everything work as expected. Expecting the unexpected is not only wise but serves as the foundation for good contingency planning. The inherent complexity of such a system means not everything will work as planned. However, a well thought out system will provide the detailed feedback needed to make quick and accurate assessments and adjustments with predictable outcomes. Focus resources on factors under your control and where work arounds are possible. Eliminate those not under your control.

Make certain investigators have a clear understanding of expectations with regard to accelerated patient enrollment and their role in achieving it. Discussing this topic in a forthright manner with investigators at the outset of a trial will avoid miscommunication and misunderstanding later on.

Properly setting goals and managing expectations at the outset of a patient recruitment program will take project planning to the practical level and provide the basis for dynamic and effective management that will yield the sought-after results.

## Execution

Successful execution begins with obtaining advance buy-in from important stakeholders at both the sponsor and investigative sites. Nothing less than a collaborative effort will be required for a patient recruitment project to yield the desired results.

At the sponsor level, it is important to have agreement and cooperation among line personnel in all involved departments, especially the clinical, product development and regulatory teams. Staff managers in these departments along with general, finance and marketing management must also be in synch with program goals and objectives.

Start by assembling the best possible team. If possible, appoint or hire a team leader with previous experience managing proactive patient recruitment initiatives.



## Site Engagement

Site engagement is the most critical success factor when starting a patient recruitment program. The principal investigator and study coordinator at each participating site should be brought into the planning process early. At the present time, many medical device study investigators and coordinators have little or no experience with accelerated patient recruitment, and their initial reaction may be negative based on what they may perceive as an increased workload. However, almost all are motivated by a desire to conduct successful clinical research, which starts with recruiting patients as expeditiously as possible. The keys for them are ensuring the program will not increase their workload and that patients will be treated in accordance with high ethical and legal standards. A well-planned patient recruitment program should actually decrease the site workload through outsourcing some tasks and better candidate pre-screening by a centralized intermediate contact center. Faster recruitment also means the study is completed quicker and investigator “burnout” associated with lengthy enrollment times is avoided.

<b>Critical Success Factor = Site Coordinator Primary Investigator &gt; Accelerated Recruitment</b>
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Plan to incorporate information about and training for accelerated recruitment tactics at pre-trial meetings for both investigators and coordinators, and set the expectation for their participation. This is an excellent way to cement the collaborative nature of the program and their commitment to it. Prepare online training as a follow up refresher or for those who cannot attend the initial meetings in person.

Successful site engagement in advance of an accelerated patient recruitment initiative is crucial and must be carried out by the sponsor. Failure to secure buy-in at the start of a trial will sow the seeds of program breakdown and result in wasted time, money, and probable delays in trial completion.

## Piloting

Unless you have extensive previous experience with the same device and patient population in a similar study protocol, it is always a good idea to start a project with a pilot. Although complex as a whole, almost every patient recruitment program can be reduced in scale for testing, evaluating, and adjusting in advance of scaling up. Start with a pilot project that is limited in scope to a few sites with scaled down tactical elements. Carefully measure and apply lessons learned to broaden and expand program reach. Successful execution will incorporate these seven steps in order: plan, build, pilot, measure, analyze, adjust, and scale.

## Outsourcing

One or two decisions will need to be made concerning outsourcing: whether to outsource and, if so, how to select vendors.

The decision about whether to outsource all or part of an accelerated patient enrollment program is unique to each sponsoring company and clinical trial. A number of factors should be considered when making a decision, such as experience, budgetary and staff resources, and infrastructure. A good rule of thumb is to seek outside help when and where necessary. Unless your staff has deep and successful experience at proactive patient recruitment with a depth of readily available internal resources, resist the temptation to go it alone. A failed internal project will almost always have a higher monetary and opportunity cost than simply waiting for sites to recruit patients on their own.

Typically, only the largest medical device firms will have in place the experienced staff and systems infrastructure to successfully conduct accelerated patient recruitment programs. Even for many of these, an outside firm with dedicated resources for and expertise at patient recruitment and without the internal distractions inherent to sponsor organizations, will be well worth the financial investment.

If the decision is to outsource or you desire to learn more, look for firms with deep expertise in the medical device industry. Although patient recruitment has been conducted for a number of years now in the pharmaceutical sector, medical device trials and patient populations are very different and patient recruitment for these trials is still relatively new. Check to see whether a patient recruitment firm has the resources to successfully execute a program, such as technical and creative development, and the necessary staff with bandwidth for the expected demands of your project. Look for internal capabilities such as a contact center and expertise in such disciplines as web and media development, planning, and purchasing. Request a high level planning document from potential vendors. Ask to see case studies and for respected industry references. One of the advantages of working with a high-quality vendor is benefiting from their lessons learned on previous projects. A well-qualified vendor will be able to share a number of these during initial interviews

The right vendor partner will combine their experience and infrastructure to produce a return many times the program investment.

<b>Outsourcing Checklist</b>	
<input checked="" type="checkbox"/>	Clinical trial experience
<input checked="" type="checkbox"/>	Medical device expertise
<input checked="" type="checkbox"/>	Staff resources
<input checked="" type="checkbox"/>	Budget
<input checked="" type="checkbox"/>	Infrastructure
<input checked="" type="checkbox"/>	Contact center
<input checked="" type="checkbox"/>	Creative services
<input checked="" type="checkbox"/>	Web
<input checked="" type="checkbox"/>	Media development, planning & purchasing

# Summary

This article is intended as a primer for accelerating patient recruitment for medical device clinical trials. Many of the topics are covered herein at a summary level, and are not intended to serve as an exhaustive resource for project planning and execution.

If one area should be emphasized, it is that the old adage to “**plan the work and then work the plan**” certainly holds true for proactive patient recruitment. It is not necessary to embark on a monolithic project to achieve faster recruitment. Even a tactical plan that addresses a couple of key processes at a handful of sites can yield positive results if thoroughly planned in advance and then executed correctly.

In order to make an advance determination of the relative value of accelerating patient recruitment for a given trial, the questions that need answering are: what is it worth to the sponsor? What will it mean if a particular trial can be completed six, twelve, or even eighteen months faster? If the benefits accruing from such results are worth the investment, then the answer is self-evident.

Last, accelerating patient recruitment is not intrinsically difficult. It simply requires people with the experience to design and implement a good system and the subsequent time and attention to detail to manage it to achieve results, along with some dedicated infrastructure. An effective system will accomplish two things: **(1) link the interactions that already take place between patients, sites, and sponsors into a seamless network of interconnected and measurable exchanges that can be carefully tracked and adjusted to generate expected outcomes, and (2) increase the flow of patients into the network.**

For most medical device firms, accelerating patient recruitment represents an opportunity that should be mastered to maximize growth and competitiveness.

## About the author

*Mark Summers is a thought leader, industry expert and innovator. As founder and Chief Executive Officer of ThreeWire, Inc., he has applied his substantial and diverse knowledge gained through more than twenty years of industry experience to the development of new marketing, clinical trial recruitment and patient engagement models for the medical device industry.*