

REINVENTING PATIENT RECRUITMENT

Revolutionary Ideas for Clinical
Trial Success

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GOWER

**“THE GREATEST DISCOVERY OF MY GENERATION
IS THAT MAN CAN ALTER HIS LIFE
SIMPLY BY ALTERING HIS ATTITUDE OF MIND.”**

JAMES TRUSLOW ADAMS

CHAPTER ONE

PUTTING THE PATIENT FIRST

IN THIS CHAPTER

- Why patient needs must remain the primary focus throughout a clinical study
- Applying the four “Ps” from marketing science to clinical study planning
- Good Recruitment PracticeSM (GRP)
- Reframing the patient’s relationship to the study via informed decision
- GRP in action: making every patient interaction count

PLANNING A CLINICAL TRIAL: WHERE MARKETING SCIENCE MEETS MEDICAL SCIENCE

In the past, when patient recruitment was synonymous with advertising, a few hastily prepared print ads and patient brochures seemed sufficient to check patient recruitment off the to-do list. Times have changed. Today, meeting patient enrollment goals in a clinical study requires more planning and a variety of sophisticated services and programs, among them:

- Feasibility modeling and analysis
- Site selection, training, support and consultation
- Metrics and evaluation
- Advertising
- Public relations.

Instead of seeing patient recruitment as a one-time task, imagine it as a dynamic process integrated into every aspect of clinical study development, from protocol design to metrics and evaluation. Why? Because only when clinical scientists focus on patient needs *throughout* the planning process will they be on the way to successfully enrolling a study, on-time and on-budget.

Yes, we *are* talking about a fundamental change in attitude that must be adopted by everyone associated with the study. The new mantra: “Put the patient first!” It’s the best way to keep patients motivated throughout the study—and motivated participants are more likely to be retained for the duration of that study.

So, how do you begin effecting this attitude shift? Two ways. One is to rigorously apply the principles borrowed from the science of marketing. The second is to view each study as an evolving entity where all elements are considered concurrently and patient needs and concerns are incorporated all along the way. That’s what we call Good Recruitment PracticeSM (GRP). Together, they make a formula for a successful study.

APPLYING MARKETING PRINCIPLES

Marketing experts rely on the four “Ps” when they plan a campaign: *product*, *price*, *place* and *promotion*. If they were marketing a hypothetical convertible in the US, the car itself would naturally be the *product*. The *price* might be \$32,000. Since most people who purchase convertibles live in mild climates, the West Coast of the US might become the target *place*. And if a market analysis showed that buyers are likely to be young professionals with day

The leading cause of missed clinical trial deadlines is patient recruitment, taking up to 30 percent of the clinical timeline.ⁱ

jobs, the *promotion* campaign might include direct-to-consumer television advertising during evening hours.

It's just as productive to apply these same four "Ps" to the clinical research planning process except that:

Product equals *protocol design*

Price equals *benefit of participation*

Place equals *site locations*

Promotion equals *messages and materials* used for outreach to target audiences

Only we also need to add a fifth "P" to represent the *patient* (see Figure 1.1.), because patient needs must be the focus of every aspect of the critical planning phase.

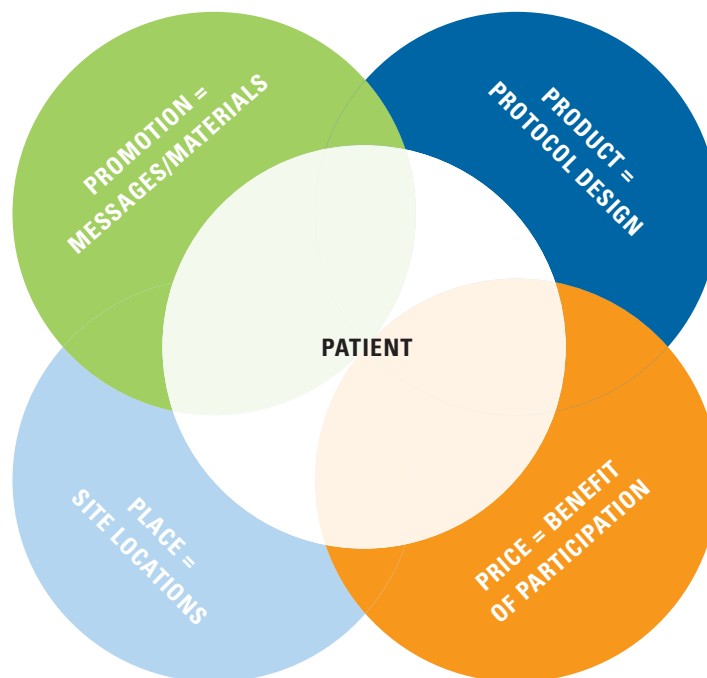


Figure 1.1 The five "Ps" of patient recruitment

Remember too that all five "P" concepts (including *patient*) evolve as study planning unfolds and each impacts the others. For example, a seemingly minor decision to change a study from 52 weeks to two years (a change in the *product* or protocol design) could affect all of the other "Ps." First, the type of *patient* interested in participating in a one-year study might not be interested in a longer-term trial. The two-year period might interest more uninsured patients who don't already have a relationship with a doctor and who may

value the peace of mind that steady care over two years could bring to their lives. So, both the patient motivation and the *price*, or perceived benefit of participation, changes. These changes, in turn, call for an altered approach to *promotion*—the messages and outreach materials you use to reach your target audience. Finally, the *place*, or which sites you choose, may change as well—based on where you will be most likely to find the type of patients you identified, and how far they may be willing to travel on a regular basis for the course of the study.

APPLYING GOOD RECRUITMENT PRACTICE

GRP is a BBK Worldwide industry initiative that both articulates and embodies a patient-focused attitude. We believe it forms the foundation for all successful patient recruitment activity. Similar in spirit to the Good Clinical Practice (GCP) guidelines for designing and conducting research studies, GRP cultivates a positive, dynamic and productive relationship between site staff and patients. A GRP approach also helps recruit physicians as investigators, because it combines the best practices of clinical research with the marketing science of healthcare communications. Another important benefit—it fosters awareness and education, improving public perception of clinical research.

THE THREE BASIC PRINCIPLES OF GOOD RECRUITMENT PRACTICESM

1. Design studies with patient recruitment in mind.

Incorporating GRP from inception saves sponsors time and money while protecting the patient experience from initial inquiry through participation.

2. Put patients first to benefit the entire medical research system.

When you make optimized patient care a benefit to study participation, you improve patient, physician and public perceptions of clinical research.

3. Help patients make better healthcare decisions.

Providing thoughtful, thorough and sensitive communications will further patients' understanding of a disease category and enhance their ability to better care for themselves both during the study and in the future.

GRP principles guide study sponsors, investigators, study coordinators, referring physicians, recruitment service providers, institutional review boards (IRBs) and others (the *study community*) through decisions involving patient information and communications, study design, planning and conduct, investigator-referring physician relations, incentives, disclosures, and public awareness and education.

When members of the study community embrace GRP, they share common goals, some of which include:

- Increasing participation of patients and physicians in clinical studies
- Empowering patients to make better-informed decisions about study participation
- Enhancing the experience of clinical study participation for patients and physicians
- Fostering awareness and education about clinical research
- Improving communication among all parties involved in the clinical research and development process
- Supporting ethical behavior and decision making related to potential conflicts of interest
- Reducing delays and costs in the development of drugs, devices and other treatments.

THE PATIENT'S RELATIONSHIP TO THE STUDY: REFRAMING INFORMED CONSENT

One particularly important aspect of GRP concerns how we view *informed consent*. When a patient gives his or her consent, he or she agrees to the terms as outlined and signs the consent form. At that moment, an important bond between patient and study is created, but not necessarily one that is strong enough to carry the patient through the study's duration. Many participants, especially those for whom the study offers access to investigational treatments otherwise unavailable, may sign the document in the heat of the moment, only to reflect later that they have not fully understood everything they agreed to.

GRP suggests the preferable model of *informed decision*. The concept of informed decision advances the idea of informed consent by adding the dimension of the patient's ongoing experience. A participant actually makes an informed decision to participate in a study on a daily basis. These decisions are based on many factors, not the least of which is the continuing experience as a participant. When patients make informed decisions, they become more invested in a process they feel a part of, not apart from.

There is a significant difference between the static moment in time when a patient signs the informed consent form and the desired, ongoing state of mind GRP defines as informed decision. It's probably fair to say that fostering an informed decision is a proactive—rather than reactive—approach to both

Eighty-six percent of clinical trials fail to enroll on time, with 52 percent delayed by one to six months.ⁱⁱ

communicating with patients and supporting them through the recruitment and retention process. It also opens the door to *informed participation*, where patients feel empowered to take ownership of their experience, communicate with healthcare professionals actively throughout the course of the study, and make conscious choices at every stage. Ultimately, the goal of GRP is to improve the benefits to patients who participate in clinical research studies, as well as to those who ultimately receive the approved treatments that come from clinical research.

GRP IN ACTION: MAKING EVERY PATIENT INTERACTION COUNT

Everyone recognizes quality customer service. When we happen to be on the receiving end, we know just how memorable these moments can be. Our industry needs to apply the same techniques to all patient interactions throughout a clinical study, seeing patients as “customers” who are crucial to achieving the goals of the study. By following just five basic principles, the study community will positively influence their working relationships, as well as patient satisfaction and retention:

1. Healthy Attitude

Every study community should make interpersonal skills a priority. A friendly greeting, warm smile, careful listening and sincere thank you leave a lasting impression, encourage co-workers to do the same, and help motivate a patient to continue participating in a study. These are easy, positive and universal social cues that help people connect to one another. Conversely, inattention, frowns, arguing and ignoring leave an unfavorable impression.

2. Know Thy Patient

Recognize that all people, including patients, share basic human needs. They want to be treated with dignity, respect, understanding and appreciation. Site staff training should include guidelines for how patients should be treated during telephone calls and site visits.

3. Every Contact Counts

Every interaction with a patient influences the patient’s willingness to comply with the study requirements and remain fully committed to its completion. So, each study community has to commit to *consistently* demonstrating courtesy and respect, essential elements in building the kind of solid relationships necessary for study success.

The demand for respondents to clinical study promotions increased approximately sevenfold between 1999 and 2005, from 2.8 million to 19.8 million.ⁱⁱⁱ

4. Keep It Simple and Sensible

People naturally resist anything that is complicated or confusing. Clear communication, both written and verbal, will support patients at all times during the study.

5. Practice Makes Permanent

Demonstrating positive interpersonal habits is contagious. When people generate goodwill among patients and staff they become models for others and make the workplace more productive and less stressful.¹

When everyone involved in a clinical study practices first-rate patient service, everyone wins. Satisfied patients are more likely to comply with study requirements and complete their commitment to study participation. They tend to share their pleasant experiences with friends and relatives – which not only helps study retention but also the reputation of clinical research in general. Study teams feel more positive about their workplace environment and the patients they serve, contributing to more effective study results.

Though 83 percent of Americans are willing to participate in clinical research studies, only 13 percent say they have been given the opportunity to participate.^{iv}

¹ Steve Wishnack, “Providing Meaningful and Memorable Customer Service: Here’s a Road Map to Making It Happen,” *Municipal Advocate* (June 2000), 18(4): 14-18.



PUTTING THESE IDEAS TO WORK

Here are some questions around the five “Ps” to ask yourself to apply the concepts discussed in this chapter to the practical challenges you may face.

PRODUCT = PROTOCOL

Carefully examine the protocol to discover the opportunities, challenges and variables inherent in this particular study. There’s a lot of information to glean that can both help and hinder your study.

Consider that you are mining for factors of “recruitability”:

- Is the informed consent form simple or will all those warnings add up to total discouragement on the part of a prospective participant? Is the language easily understandable by the patient?
- How rigorous are the inclusion and exclusion criteria? Do they limit the patient pool to too small a number?
- Are participants more likely to view the number of study visits as careful monitoring or unnecessarily time consuming?
- Can visit procedures be designed to encourage patient compliance and retention?
- How onerous is the wash-out period? Is there an open-label treatment option that appeals to patients?
- Is there a rescue therapy provision allowing patients who don’t do well in the study to switch to alternative treatments?
- Is a placebo involved that tends to discourage patients who are suffering?

PRICE = BENEFIT OF PARTICIPATION

In any clinical study you have to consider the motivations of all players: staff, patients and sites.

Participating in a study should be worthwhile for *everyone*:

- Does the study’s compensation structure encourage participation? For example, are sites compensated for patients who fail the first screening as well as patients enrolled?
- Is reimbursement for procedures, equipment and screenings likely to motivate the staff?
- Are there sufficient resources to guarantee good communication between site and patient?
- Does the protocol provide additional services to patients, like screenings, nutritional consultation, or fitness or rehabilitation plans?
- What costs will patients incur from participating? Can any of these costs be covered by the study?
- What details might help motivate the various potential audiences (that is, patients, influencers, principal investigators and study coordinators)?



PLACE = SITE LOCATIONS

Since choosing quality sites is the foundation of a successful study, you'll want to see how the protocol impacts site selection:

- What information from the protocol can you use to paint a picture of who might make an ideal PI?
- What is the site capacity for scheduling and processing patients for optimum convenience?
- Is the site sufficiently staffed to handle a large number of referrals and screenings?
- What training is needed to prepare the site staff?
- How prevalent is the disease state in the area near the site?
- Is the site in a more populated urban setting or less dense suburban area?
- Does the site's geographic location impact patients? Is it convenient or difficult to get to?
- What is the local standard of care and how might that influence the patient's willingness to participate?
- Is the site conducting other studies that might impact recruitment for your study?

PROMOTION = MESSAGES/MATERIALS

Each protocol includes information key to understanding your audience, empathizing with the audience mindset, and creating effective communications:

- What are the demographics of this study? Is the target audience young or old? Male or female?
- Consider your audience's psychographics. What thoughts, concerns and feelings are people with this condition likely to have?
- What kind of message is your audience most likely to respond to?
- Should outreach be targeted to patients, caregivers, family members, or physicians?
- Which media delivery vehicles are most likely to reach your target audience?
- What are the local costs involved in media outreach and does the budget plan for these expenses?
- What options exist if a call center is needed?

RESOURCES

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Notes

- i PRNewswire, "Patient Recruitment Plays a Major Role in Meeting Clinical Trial Deadlines" (Research Triangle Park, NC: Author, August 31, 2005): 1. Press release.
- ii PAREXEL's Pharmaceutical R&D Statistical Sourcebook 2003/2004 (Waltham, MA: PAREXEL International Corporation, 2003): 112.
- iii N.S. Sung et al., "Central Challenges Facing the National Clinical Research Enterprise" *Journal of the American Medical Association* (March 12, 2003): 289(10): 1278–1287.
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