Patient Recruitment

Road to Success or Driving in Circles?

Opportunity
NEXT EXIT

PATIENT AND INVESTIGATOR RECRUITMENT

WHAT WORKS?
WHAT DOESN'T?
WHAT'S NEXT?

"What should be available to the industry is a 360° assessment of the performance, drivers, motivations, hesitations, and leading edge techniques of patients, investigators, pharmaceutical companies, and pharmaceutical service organizations. Getting that view of patient recruitment would be highly beneficial to the entire industry. Without getting on too high of a soapbox, the delays in patient recruitment not only have monetary impacts, but they have patient well-being impacts as well."
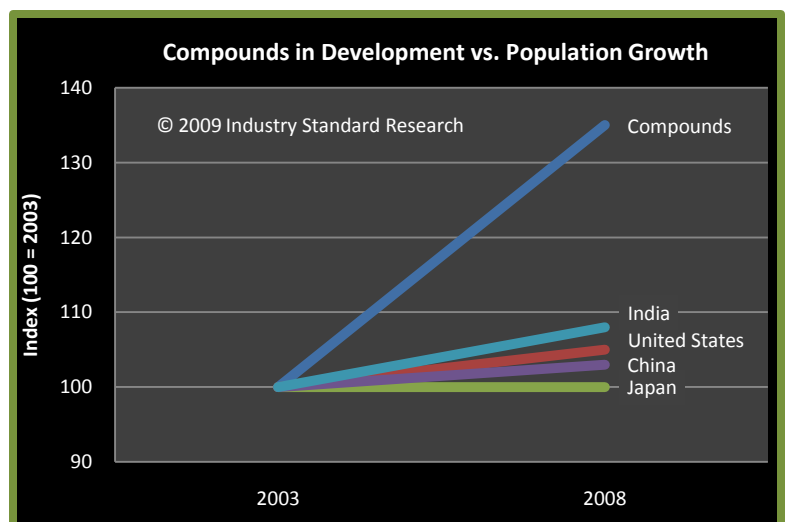
$360°$ Evaluation

- Investigators
- Patient Recruitment
- Patients
- Patient Retention
- Pharma CRO
- Feasibility

Introduction

If you are at all familiar with the clinical development industry, then you already know the figures:

✓ According to the Tufts Center for the Study of Drug Development, less than 10% of clinical development studies are completed on time.

✓ CenterWatch has reported that roughly 70% of all trials are delayed from one to six months due to patient enrollment problems.

✓ Delays in the drug development process cost pharmaceutical companies billions of dollars per year. For example, a conservative estimate on lost sales per day in the United States would equate to $2.2M. *(www.drugs.com reports that in the U.S. in 2007 the 50th best-selling drug (Actonel) generated $2.2M in sales per day)*

✓ According to a citation at www.ciscrp.org, the number of active investigators in the US has declined 3.5% annually since 2001, whereas active investigators outside the US has increased 13.5% each year during that same period. *(Getz, Zuckerman and Rochon, "Landscape changes highlight growing challenges for clinical research sponsors" 2009)*

The industry knows the issue at hand – it is not new and it is not solved. Read the press releases, study the magazine headlines, or look at what companies are exhibiting at major industry trade shows and it becomes strikingly evident: patient recruitment and retention is an industry issue and many companies have positioned themselves to take advantage of this opportunity. And make no mistake, it is an opportunity. The number of trials is growing at a rate far faster than the population and the range of studies is narrowing making competition for patients real. For-profit companies, not-for-profit companies, industry steering committees have all been formed to address this issue/ opportunity. The Patient Recruitment Organization Steering Committee was formed in 2009 by companies representing specialized patient recruitment organizations and CISCRP, a non-profit organization that has been around for several years advocating for clinical trial education, are just two such organizations.
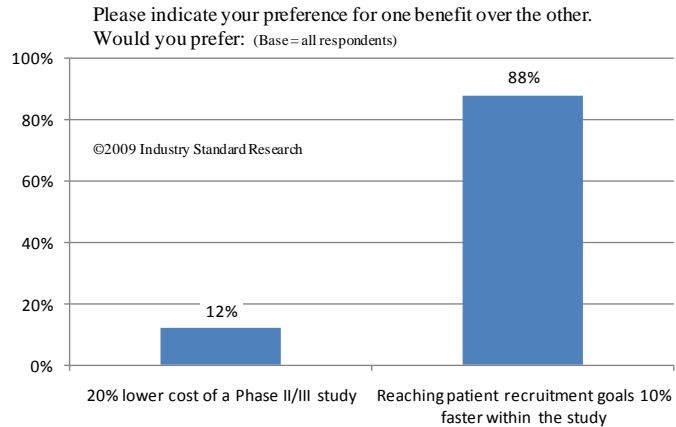
The four citations at the top of this page are just a sampling and we had literally dozens of others we could have used. The pharmaceutical and pharmaceutical service industry does not need to be made aware of the patient recruitment issue. They need suggestions on how to solve it. The industry needs a front-line assessment of how things work in the physician's office, what motivates patients, how pharmaceutical service providers perform, and data on the most effective techniques for patient recruitment and retention; it needs a 360^0 evaluation of the issue.

Compounds in Development vs. Population Growth

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Index (100 = 2003)

Compounds / India / United States / China / Japan

2003 — 2008

**More studies competing for relatively fewer patients.**

Importance of patient recruitment

From our own analysis we have discovered the power of asking the right questions. The information on the right is taken from our inaugural CRO Benchmarking report released in March 2009 (www.ISRreports.com). This report, which analyzed the responses of 160 pharmaceutical and biotech clinical development decision-makers, highlighted some of the very issues we have previously discussed. Their preference to speed the patient recruitment process by 10% over receiving a 20% price reduction on a study makes sense perfect economic sense (remember the $2.2M of lost sales per day), however the fact that nearly 90% of people felt the same way confirmed for us that patient recruitment and retention is one of the burning issues for the industry.

Please indicate your preference for one benefit over the other. Would you prefer: (Base = all respondents)

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Performance assessment

The fact that only a few CROs even meet sponsors' expectations for patient and investigator recruitment and that over half of the pharmaceutical development decision-makers surveyed could not name a market leader in patient and investigator recruitment only reinforced the situation. But what about other "service providers" and the pharmaceutical companies themselves, how are they doing?
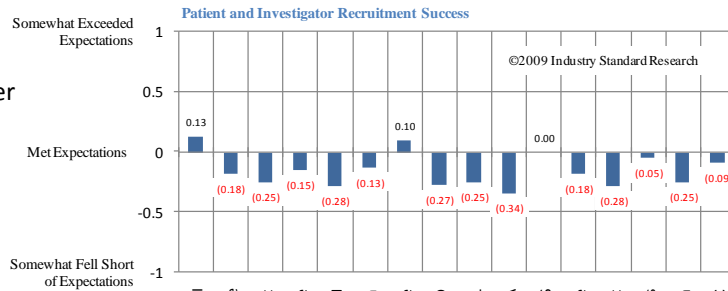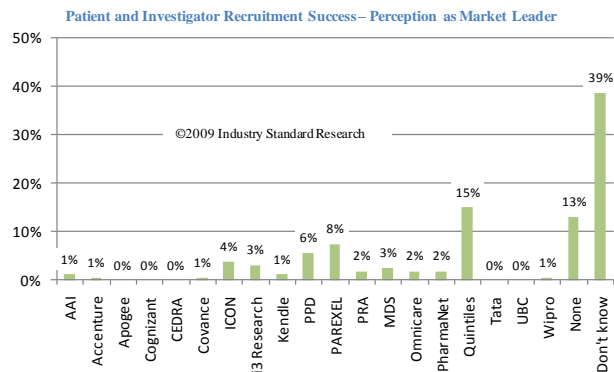
Why the underperformance?

Think about all of the inputs and contingencies that would go into assessing the performance of patient recruitment. Simply evaluating whether the number of patients recruited tracks to a timeline might be too simplistic a measure. You have to ask yourself, how was the timeline created in the first place, who was involved, and what processes/ rigor did they follow? Often there are a multitude of very distinct parties involved in the end-to-end patient recruitment process:

•The sponsor who developed the protocol

•One or more parties who conduct feasibility studies

•One or more organizations or departments that select the sites and principal investigators

•One or more parties who determine the patient recruitment strategy

•One or more parties execute the patient recruitment strategy.

Then we wait. As studies show us, there will most likely be delays in patient recruitment, but why? Unraveling the complexities to answer the "why" question is necessary to improving the entire process.

Patient and Investigator Recruitment Success

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Patient and Investigator Recruitment Success – Perception as Market Leader

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COMPLEXITY

Trial complexity…

We don't think anyone would object to the statement that clinical development studies are more complicated today then they were five or ten years ago. In fact, Tufts has presented some great statistics illustrating just how much longer trials take and how many more inclusion and exclusion criteria exist in today's studies than in years past. Let's take a look back to what has brought us to this point.

…breeds specialization…

Clinical development has become more complex and has morphed into highly specialized disciplines. Whether it is the inner workings of a large pharmaceutical company or a combination of the myriad of outsourced service providers, one can find "specialists." Want someone to provide your IVR? You can find someone? Want someone to manage your EDC? You can find someone. Want someone to manage your site start-up? You can find someone. And yes, if you want someone to manage your patient recruitment you can find dozens of options. Specialization is not a bad thing and it's brought about by opportunity arising from missed expectations/ poor performance and robust industry economics. But with specialization comes the addition of many more moving parts and interested parties. And these numerous moving parts obscure the key inputs that make a clinical trial work: the physician and the patient.

…which makes problem identification difficult.

So this begs the question: when a statistic is produced that says the majority of clinical studies are delayed due to patient enrollment problems, is this due to poor patient recruitment and retention strategy and execution or to poor feasibility and expectation setting? To be honest, we don't know, but we think someone should start looking into it because the ramifications could be game changing for the drug development industry.

Are these easy questions to solve? No. Can we solve it just by talking to drug development organizations? No. Can we solve it by simply talking to patients or potential patients? No. Why not, you ask. Because the issue is complex, has many moving parts, and the causal relationships between variables are unknown. As an example, let's take a somewhat simple hypothetical question: What do you think would impact patient recruitment and retention more: (1) having a highly motivated principal investigator, or (2) a rock-solid patient recruitment and retention strategy? Again, we don't know and we think that some high gain questions like that need to be asked.

What *should* be available to the industry is a 360^0 assessment of the performance, drivers, motivations, hesitations, and leading edge techniques of patients, investigators, pharmaceutical companies, and pharmaceutical service organizations. Getting that view of patient recruitment would be highly beneficial to the entire industry and because, without getting on too high of a soapbox, the delays in patient recruitment not only have monetary impacts, but they have patient well-being impacts as well.

360° Evaluation — Investigators, Patient Recruitment, Patients, Patient Retention, Pharma CRO, Feasibility

Feasibility

The feasibility analysis sets the expectations for the trial and all too often the industry takes it as gospel. Regardless of whether someone says a study should take four months or nine months, the fact is it still takes finding qualified and motivated principal investigators to participate in a study, making potential trial patients aware of the study, getting them to the clinical site, enrolling them, and keeping them engaged until the study completes. However you slice it, more information is needed from investigators, site coordinators, and patients before and during a clinical development study in order to ensure that high quality patients are enrolled as quickly as possible and stay enrolled to study completion. According to our sources, the single largest complaint from principal investigators (PIs) is that they are not given enough information on which to make an educated decision; they are asked to comment and give patient recruitment estimates based on very little study information.

Ask more questions...

More information is needed around assessing the rigor (or lack there of) that was undertaken during the feasibility stage of protocol development, site selection, and patient recruitment estimations. Some questions that need to be asked include:

- ✓ Were any third party sources of medical data (electronic medical records, prescription drug scripts, HMO claims) used to determine the potential patient population?
- ✓ Who reviewed the protocol? Key opinion leaders, who may or may not have seen a patient in years, or practicing physicians?
- ✓ Were site selection and patient recruitment estimates gathered in an environment whereby the Principal Investigators did not have access to the final protocol?
- ✓ How many investigators or site coordinators were given a market research questionnaire to determine their ability to recruit patients or have interest in participating in the trial?
- ✓ Were patient drivers of study participation and avoidance assessed? How can these be responsibly leveraged / overcome?

...using more formal methodologies.

Most people have heard of the market research technique/ methodology called the Voice of the Customer (VOC). We, as market research professionals, strongly believe in the notion that collecting first-hand feedback, suggestions, and barriers from customers is time and money well spent. However, VOC works well when you actually know who the customer is. And in the end, the customers of the pharmaceutical companies – and by extension, the pharmaceutical services organizations – are: (1) Doctors, Physicians, Clinicians, Investigators and (1) Patients. And "no" we did not make a typo (at least not here) by placing a (1) in front of both Physicians and Patients because we believe both are equally important. What the drug development industry needs is a Voice of the Patient (VOP) and Voice of the Investigator (VOI) analysis. It is our hypothesis that if more sponsors, CROs , AROs , and/or patient recruitment agencies used these 360^0 techniques that many of the ills faced in the recruiting and retaining of clinical trial patients would be solved. We need to triangulate the thoughts, perceptions, and performance from multiple stakeholders in order to accurately assess the situation.

Would developing processes and techniques to capture the Voice of the Patient and Investigator take more time, resources, planning, and money? Yes it would. Would it cost more than a day's sales? Now that's unlikely.

Summary

Is patient recruitment and retention one of the most pressing issues for the pharmaceutical industry? Yes.

Is that finding industry-changing? No.

The drug development industry does not need another analysis that identifies patient recruitment and retention as a high-priority issue. What we need is an analysis of what to do next to solve the problem or at least how to frame the right questions. At its essence the problems of patient recruitment and retention could be greatly improved if we, as an industry, could answer the following three questions:

1 What methodologies are having the greatest impact and which organizations are performing the best?

2 What are the motivations and barriers for patients and investigators to participate in clinical trials?

3 What are the best and leading edge techniques?

In the end, this is complicated, but oh-so-full of opportunity. Just imagine the possibilities for the organization that cracks the code and can guarantee patient recruitment and retention schedules. That is game-changing.

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www.ISRreports.com
info@ISRreport.com

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