



LEO J. SHAPIRO & ASSOCIATES L.L.C.

Clinical Trials Recruitment:

The Bigger The Pool, The Better For Everyone

Billions of dollars are spent on clinical trials each year, a sizeable portion of which is spent on patient recruitment. Recruitment delays extend drug and treatment development times, significantly raising costs and slowing time to market. The demand for candidates is so high that identifying and recruiting eligible patients for pharma companies has become a booming business. Unfortunately, even these efforts are not enough to meet the growing demand for trial participants.

NEW STUDY: PUBLIC OPINION OF CLINICAL TRIALS

There is hope for improvement, however. Chicago-based market-research firm Leo J. Shapiro & Associates (LJS) conducted a study in January 2007 indicating that the pool of potential candidates for clinical trials is much larger than the pool currently being tapped by researchers, and that more effective communication with this broader pool of candidates could help speed time-to-market and reduce clinical development costs for all.

To understand current public thinking about clinical trials, and to find out what some of the limitations to clinical trial participation might be, LJS conducted a national study of 450 households. Each household was selected from a random sample of the national population to participate in a telephone interview on the topic.

KEY FINDINGS:

- 1) The patient pool can be enlarged
- 2) Public support for clinical trials is widespread
- 3) Awareness of trials tends to generate support for them

STUDY RESULTS

The findings of the study indicate that many Americans who have not participated in clinical trials are open to participating in them.

- Many of these people have not heard or read about clinical trials, but would consider participating if they were eligible.
- A majority of the respondents said they believed clinical trials help the patients involved and contribute significantly to the advancement of medicine and healthcare.
- A majority also indicated that they would seek out more information on a clinical trial if it pertained to them.
- Finally, most people who had participated in trials reported having positive feelings about the experience.

All of this bodes well for those interested in broadening the pool of eligible candidates for clinical trials. The LJS study suggests that there are a significant number of people in the United States not currently participating in clinical research who would consider taking part in a clinical trial if they knew about it, and if they were deemed eligible. The study also suggests that current outreach, recruitment and retention efforts are not as effective as they could be, and that improvement in this area would be a positive step toward controlling the increasing cost of clinical development.

Leo J. Shapiro & Associates, L.L.C. is a consumer marketing research firm specializing in the pharmaceutical and healthcare industries. We help companies compete by designing custom research that yields unique insights into how consumers think, feel and act.

THE STUDY

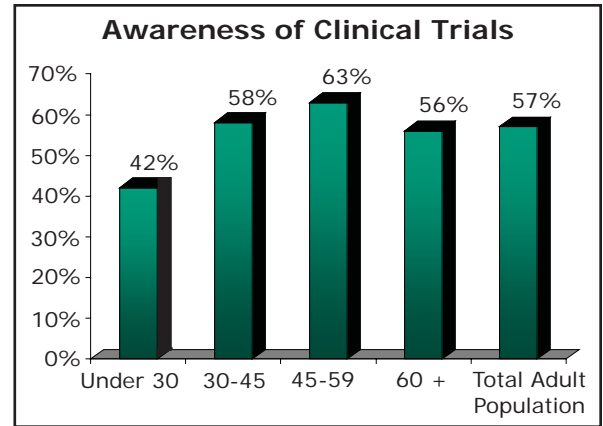
Data for the LJS study, "Public Opinion About Clinical Trials," focused on five key areas: general awareness, participation, beliefs, willingness to participate in the future, and sponsorship awareness.

PUBLIC AWARENESS OF CLINICAL TRIALS

Over half of American adults are aware of clinical trials (57%), either by reading about them or hearing about them through media exposure or other means. Awareness is related to age, rising from 42% among adults under 30 to nearly two-thirds (63%) among adults in the middle years, and tapering off at age 60 and older.

Analysis

The fact that 43% of Americans are unfamiliar with clinical trials indicates that trials have a relatively low public profile. While advances in medicine are often publicized, the news generally focuses on the benefits of medical breakthroughs and not on the clinical trials that produced them. However, the fact that 57% of American adults are aware of clinical trials suggests that the general public has at least some curiosity about how medical advances happen. Doing more to publicize trials and their benefits could raise public awareness significantly.

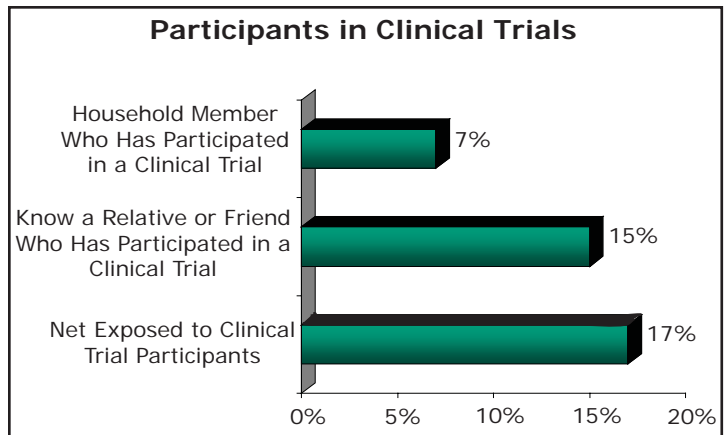


PARTICIPATION IN CLINICAL TRIALS

Clinical trials have directly touched one in six Americans. Seven percent of adults say that they or a member of their household has participated at some level in a clinical trial. Also, 15% say they know of a friend or relative who has participated in a clinical trial. Adjusted for overlap, this nets to 17% – one in six households – who have been exposed to a clinical trial through their own household or through a relative or friend.

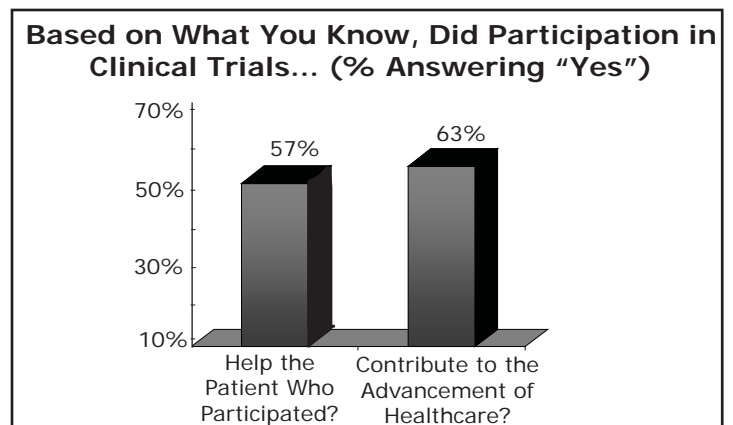
Analysis

While 17% of American households report being exposed in some way to participation in a clinical trial, either directly or indirectly, that leaves 83% of the adult population who have not. There is no way of knowing how many of those remaining people might be eligible for a clinical trial, but the percentages suggest that at the very least there are millions of potential candidates who, for one reason or another, have not been exposed to clinical trials.



BELIEFS ABOUT CLINICAL TRIALS

Most people (57%) who have been exposed to clinical trials, either directly or through family and friends, believe that patients are helped when they enroll in a clinical trial. Even more (63%) believe that clinical trials contribute to the advancement of medicine and health care.



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Analysis

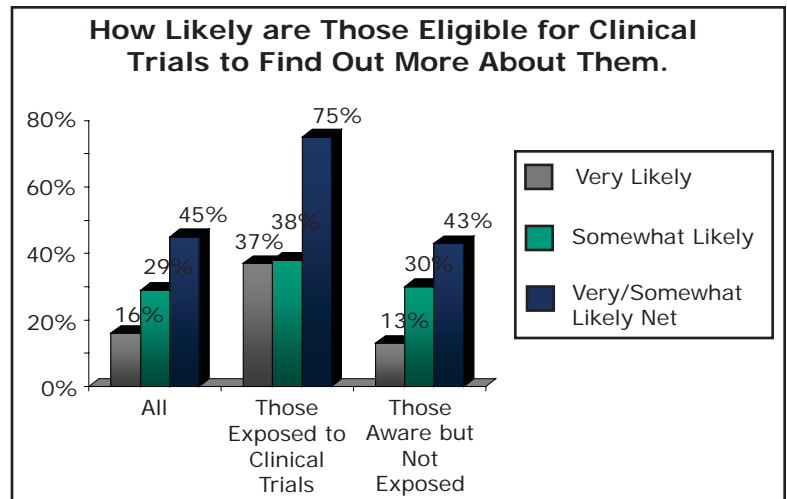
High percentages of people who have been exposed to clinical trials believe that they help patients and advance the cause of medicine. This is important for a number of reasons. For one thing, as the data in the next section suggest, those who know people who have had a positive experience in clinical trials are more likely than not to be favorably disposed to the idea of participating in a trial themselves at some point. Positive feelings toward clinical trials reported by people who have been exposed to them also suggest that a generally positive pattern of influence exists between trial participants and the people who know them. This pattern of positive association is one the industry could potentially leverage to spread feelings of acceptance and appreciation for clinical trials in the rest of the population.

ENTRY TO CLINICAL TRIALS

Nearly one in two U.S. adults (45%) are open to inquiring about a clinical trial for which they might be eligible. This percentage rises to three-fourths among those who have been exposed to a clinical trial. The determination to follow through is greatest among those who have been exposed to a clinical trial.

Analysis

In general, it appears that the more information people have about clinical trials, the more positive their impressions are. Furthermore, those who have been exposed to clinical trials are the ones most open to gathering more information about them, as well as the ones most likely to participate in future trials. This data suggest that raising awareness of clinical trials through more and better information, and by promoting active communication by trial participants among their family and friends, is likely to broaden the pool of candidates who are interested in participating in trials. Exposing the broader population to messages about the benefits of clinical trials is also likely to increase the number of people who think favorably toward clinical trials.

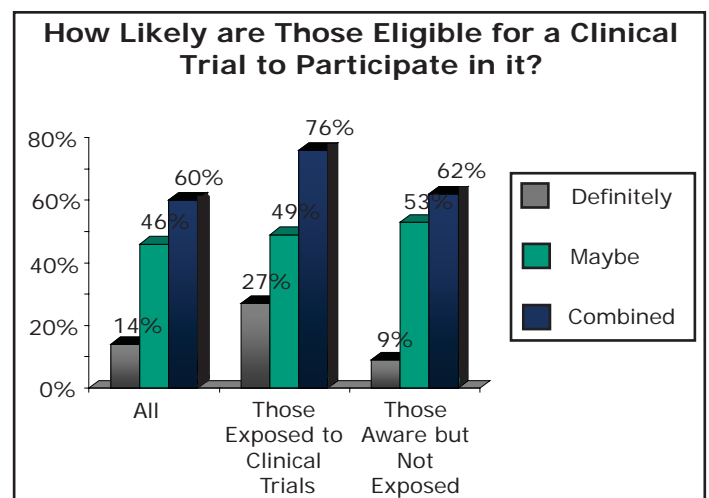


THE ENROLLMENT DECISION

Most patients view the possibility of participating in a clinical trial as an attractive opportunity, as long as their doctor approves. If they were deemed eligible for a clinical trial, and their doctor approved participation, one in seven adults say they would definitely enroll. This rises to 27% among those who have had direct exposure to clinical trials among family or friends. Significantly, another 46% of all adults say “maybe,” when asked if they would enroll. Thus a majority – 60% – of the adult population is open to participating in a clinical trial if they are found eligible and their doctor approves.

Analysis

This finding indicates that the public’s inclination to take advantage of clinical trials is substantial. Again, this finding supports the general notion that the more information people have about clinical trials, the better. Doctor approval is the key. As we reported in our November 2006 newsletter, people’s doctors are their primary source of information about prescription drugs, and they place an extremely high value on this information relative to other sources. People are likely to weigh their decision to enroll in a clinical trial on a number of different factors, including the severity of their own health



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issues and the treatment alternatives available to them – but their doctor’s advice is likely to have the most influence on their decision to actually enroll. Therefore, finding ways to facilitate a more informed dialogue between doctors and their patients about clinical trials is likely to result in more patients who are willing to take advantage of the opportunity that clinical trials represent, both for improving their own health and contributing to the advancement of medical science in general.

SPONSORSHIP AWARENESS

One component of awareness about clinical trials is knowledge of who sponsors clinical trial studies, and why. When asked, most people aware of clinical trials think they know who sponsors them (80%). Over half say clinical trials are sponsored by drug companies (56%). Only 14% say they are sponsored by doctors or hospitals, and 9% by universities.

By and large, sponsorship does not influence the decision to enter a clinical trial. The percentage of people definitely prepared to participate in a clinical trial is virtually the same regardless of who they think is the sponsor. However, the percent who say they might participate (“maybe”) is greater when they think the trial has university sponsorship than for other sponsors.

As Far as You Know, Who Sponsors Clinical Trials?				
% Of All Aware Of Clinical Trials (multiple responses) (n=257)		Likelihood of Participation in Clinical Trials if Eligible		
		Definitely	Maybe	Definitely Not
56%	Drug Companies	17%	44	38
14%	Hospitals, Doctors	17%	40	43
9%	Universities	15%	68	17
17%	Other (research, groups, product developer, public	12%	58	28
20%	Don't Know	10%	44	40

Analysis

In reality, clinical trials are conducted by a wide variety of groups, including pharmaceutical companies, private medical institutions, foundations and universities, as well as federal agencies such as the National Institute of Health (NIH). To potential trial participants, however, the sponsor of the trial is not as important to their decision to participate as the likelihood that the trial will benefit them personally in some way. The public places a somewhat higher degree of trust in university-sponsored trials, presumably because of the perception that universities are primarily seeking scientific knowledge, not profit. Nevertheless, the fact that a trial is being sponsored by a drug company does not appear to be a significant deterrent to those who wish to participate.

IMPLICATIONS AND RECOMMENDATIONS

In the United States, the generally positive climate for clinical trials, particularly among those who have participated in them or have been exposed to them through friends or family, should be viewed as evidence that further support for clinical trials can definitely be cultivated. There is a direct correlation between people’s attitudes toward clinical trials and the amount of exposure they have had to information about trials. The data suggest that the more information people have about clinical trials, the more likely they are to think favorably of them, and the more likely they are to consider participating in a trial if eligible.

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Enlarge The Pool By Sharing Information

Considering that 83% of the population has had no experience with clinical trials whatsoever, it is reasonable to suppose that there are millions of potential candidates in the U.S. who are not receiving enough information about clinical trials to make an informed decision about whether they could or should participate. This means that bringing clinical-trial opportunities to the attention of more people is likely to result in a broader pool of potential candidates. Furthermore, the fact that so many Americans who know about clinical trials view them positively should encourage the pharmaceutical industry to expand the public's knowledge of them. In theory, broadening the pool of candidates from which clinical-trial patients can be drawn should make it possible to identify eligible patients more efficiently, reducing the time it takes to launch a clinical trial, as well as the costs associated with it.

Educate The Public About Trials

A broader public understanding of the critical role clinical trials play in advancing medical science is also likely to improve the public perception of clinical trials in general. Currently, most people hear about clinical trials when something goes wrong. A more informed understanding of the risks and rewards of clinical trials could help mitigate the damage done by disproportionate press coverage of tragic outcomes. Those who become newly aware of clinical trials are also likely to view them as a source of personal or potential health benefits, further broadening the support for such trials in the future.

Spread The Goodwill

Better communication with physicians is another area ripe for improvement, especially since most patients rely on their doctors for information about clinical trials for which they might be eligible. The pharmaceutical industry should also search for better ways to leverage the good will generated by people who participate in trials. Knowledge of the potential health benefits from participating in trials, coupled with the knowledge that broader participation in clinical trials can help reduce clinical development costs and might also to be a catalyst for public support.

Let Them Find You

The pharmaceutical industry should continue to strive to make the public more aware of ways they can find out about clinical trials on their own. Numerous sources exist on the Internet at such sites as www.ClinicalTrials.gov, www.trialscentral.org, and www.medlineplus.gov, all of which are great resources. But more can surely be done to put this information in the public's hands. We live in a society in which people are being forced to take more responsibility for managing their own health-care options. Therefore, they are more motivated to seek out information pertaining to their own health needs, including information about clinical trials that may benefit them in some way.

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Raise Awareness

There are many ways to raise the public's awareness of clinical trials. The most obvious one has to do with connecting dramatic medical breakthroughs – which almost everyone views as a common good – with the arduous and expensive process required to achieve those life-enhancing results. Those who cover medical breakthroughs in the press should be encouraged to include such information in their reporting, and those who work with the press on such stories should include clinical-trial information along with the good news.

Everyone Can Win

Steps likely to benefit both the pharmaceutical industry and the public are:

- 1) Educate the public more thoroughly about trials and their benefits.
- 2) Promote active communication by trial participants with their friends and families about the process and outcomes.
- 3) Make specific trial information more readily available to both doctors and patients.

When the public knows more about clinical trials, our data lead to the conclusion that everyone will benefit.

If you would like to know more about LJS Pharmaceutical & Healthcare Research, visit our website at www.ljshealthcare.com. Or contact Owen Shapiro at 312.546.5960 or e-mail him at owens@ljshealthcare.com.