



Public Confidence and Trust Today^{HS}

A Review of Public Opinion Polls

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Public confidence and trust are essential to the very viability of the clinical research enterprise. Public confidence is manifest in a variety of ways, including consumer support for products and practices that have been evaluated and approved following clinical research testing and regulatory review; public support and appreciation for the professionals involved in the development and approval of new medical interventions; policymaker and political support for reforms and incentives that enable the clinical research enterprise to perform effectively and efficiently; and patient willingness to make the courageous decision to participate in clinical trials.

Investigative sites report that growing levels of public distrust have contributed to delays in bringing new treatments to market and to rising drug development costs. Since 2000, spending on patient recruitment promotional programs by investigative sites and research sponsors has grown by 12–14% annually, reaching an estimated \$500 million in 2003.¹ Enrollment rates across the United States have dropped from 75% in 2000 to 59% in 2006, and retention rates have fallen from 69% to 48% during that same period.²

Since 1998, public confidence and trust in the clinical research enterprise have eroded steadily.^{3,4,5} International and national public opinion polls provide ample evidence documenting declining public attitudes and perceptions. At the same time, however, the public remains positive in its belief in the need for clinical research to advance medical knowledge and improve public health.^{6,7,8}

Despite low levels of trust and confidence today, there is no evidence to suggest that the public will abandon the clinical research enterprise outright. A foundation of general public support exists to rebuild public confidence and trust through education and outreach initiatives geared toward improving public awareness and appreciation of the study volunteer and the value of clinical research to public health; repairing the credibility of research sponsors, study staff, regulatory, and human subject protection professionals; and engaging the public as partners in the development of new medical and health advances. Given how far public support has fallen, however, there is no time to waste in repairing and rebuilding trust and confidence.

This article reviews public attitudes and perceptions about clinical research, based on notable national and international public opinion polls,

HS Home Study article

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addresses factors that have contributed to the steady erosion of public trust and confidence, and provides thoughts on solutions to restore public support.

General Attitudes about Clinical Research

Despite frequent and highly visible negative media coverage of the clinical research enterprise, national polls indicate consistently that general public support for medical and health research remains strong and has not changed significantly during the past decade.⁶ Five years ago, a Harris Interactive poll of 1,015 U.S.-based adults found that the vast majority (83%) believe it is “very important” to “essential” that all new drugs and treatments are tested on human beings in clinical trials before they are approved for general use.⁹ Harris Interactive found a similar result in a national poll conducted in 2006.³

Research!America, a lobbying group representing academic institutions and foundations involved in clinical research, conducts public opinion polls of 800 to 1,000 American adults regularly. A 2003 Research!America poll found 91% of respondents consider funding for medical and health research to be an important (“somewhat important” and “very important” combined) national priority.⁶ In a poll conducted a year later, the group found 94% of Americans believe that medical research is important for the economy and 68% perceive clinical research as having great value for public health.⁶

Americans’ general attitudes about the value of clinical research are so strong that a high percentage of individuals appear willing to put their money behind their beliefs. In a national poll conducted by Research! America in 2005, more than half (55%) of Americans want more dollars spent on medical research. Two-thirds (67%) said that they would be willing to pay \$1 more per week in taxes, out of their own pocket, to fund that research.⁶

Polls conducted in Western Europe show similar levels of positive attitudes about clinical research among the public. In a 2004 survey of 225 Europeans, 90% considered clinical trials important, and 60% acknowledged that clinical research plays an important role in advancing public health.⁷ This survey, similar to those sponsored by Research!America, was conducted largely among individuals who have never participated in clinical trials.^{6,7}

Results from a 2007 survey of 450 U.S. households show that positive public attitudes persist; the survey found 63% of respondents believe that clinical trials contribute to the advancement of medicine and healthcare.⁸

Public Distrust in Clinical Research Professionals

Although the public clearly holds positive attitudes about the general importance of clinical research, the same cannot be said for public trust in the professionals who oversee, manage, and support that research. Distrust in clinical research professionals, and in those organizations responsible for ensuring patient safety, has increased dramatically.

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Public polls conducted regularly by the Kaiser Family Foundation and Harris Interactive present startling statistics. A 2007 Harris Interactive poll of 1,726 U.S. adults, for example, found that 27% of the public “somewhat” or “very strongly” distrusts the Food and Drug Administration (FDA). That same poll found that only 31% of Americans believe that the FDA is effective at ensuring safety, down from 56% in 2004.³ Equally alarming, nearly half (46%) of the respondents said that they distrust Capitol Hill officials who govern regulatory oversight and drug development processes.³

Four out of 10 Americans (42%) distrust pharmaceutical and biotechnology companies. The Harris Interactive poll shows that a significantly higher percentage (39%) of Americans gave poor ratings to pharmaceutical and biotechnology companies for failing to serve consumers in 2007 than did so in 1997 (19%).³

Nearly half (44%) of the 1,695 American adults polled in a Kaiser Family Foundation January 2008 survey also report having an unfavorable view of pharmaceutical and biotechnology companies. In that same survey, 27% of Americans said that they do not trust pharmaceutical and biotechnology companies to offer reliable information about drug side effects and safety, and 45% said that they do not trust research sponsors to inform the public quickly when safety concerns about a drug are uncovered.⁵

In national polls conducted in 2004 among 1,000 U.S. adults by the Center for Information and Study on Clinical Research Participation (CISCRP),⁴ only 17% of respondents reported that they consider clinical trials “very safe.” An additional 49% said that they consider clinical trials “somewhat safe.” In a similar CISCRP survey conducted in 2006, only 14% said they consider clinical trials “very safe” and 48% said “somewhat safe.”

The public displays similar levels of distrust in principle investigators and their study staff. A self-administered survey of 717 U.S. adults in 2007 found high levels of public distrust in

clinical research staff. This level of distrust was significantly higher among minority adults.¹⁰ Half (49%) of white respondents and 73% of minority respondents reported that it is “very likely” or “somewhat likely” that they might be used as guinea pigs without their consent. One out of four (25%) minority respondents and 22% of white respondents believe that their doctors would expose them to unnecessary risk in clinical trials.¹⁰

The majority of people (72%) believe that physicians get involved in clinical research to help patients find new and better treatments.⁹ Still, one out of four people believes that doctors and study staff are primarily motivated to recruit volunteers for money and selfish interests. In a 2005 survey of the general public, 25% of respondents said that they believe physicians participate in clinical research to receive money from pharmaceutical and biotechnology companies; another 20% said that physicians participate primarily for fame, glory, and publication rights.¹¹

Public Misperceptions of Study Volunteers

By extension, distrust of clinical research professionals has tainted the public’s view of clinical research volunteers. National and international polls show that a large percentage of the public considers research subjects to be risk takers who are motivated to find clinical trials because they are either greedy or desperately ill. Poor public trust and confidence, along with low awareness, have diminished appreciation for the profound gift that participation plays in helping to advance medical knowledge and improve public health.

Eight out of 10 Americans believe that study volunteers are taking a gamble with their health, according to a 2002 Harris Interactive poll.⁹ A 2006 CISCRP survey of 900 U.S. adults found one out of four believes that people choose to participate in clinical research because they are “very sick without any other options” or they are

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“looking to make money”.⁴ A smaller percentage (19%) believes that people choose to participate in clinical trials to benefit public health. In the same survey, 34% of respondents said that they “do not admire” people who volunteer for clinical trials.

As public awareness and appreciation for study volunteers have waned, public willingness to participate in clinical trials has also dropped. Research!America, for example, reported that in 2004, 55% of Americans said that they would be willing to participate in a clinical trial, down from 63% who said they would be willing to participate in 2001.⁶ A later public poll, conducted in 2007, found that only 41% of white adults and 28% of minority adults would be “very likely” or “likely” to participate in clinical trials.¹⁰

Drivers of Distrust

Numerous factors have contributed to the erosion of public trust and confi-

dence. During the past decade, the clinical research enterprise has been plagued by public skepticism and criticism of industry practices deemed questionable and deceptive. Skepticism and deep concern have been expressed about the failure of clinical research professionals to act ethically and to protect the safety of study volunteers.

Much of this attention and concern has been warranted. During the past 10 years, the media has widely publicized tragic study volunteer reactions to investigational treatments that have resulted in serious harm and death. Research sponsors and investigators have been charged and found guilty of data falsification and failures to disclose important safety information. Drugs have been withdrawn due to poor safety profiles. Physicians have been indicted for failure to disclose conflicts of interest. Research sponsors, contract research organizations, and investigative sites have been accused and found guilty of clinical trial mismanagement and failure to protect the safety of study volunteers. Human subject protection programs have been charged and suspended for failing to provide adequate oversight. Pharmaceutical and biotechnology companies have been publicly challenged for submitting fraudulent safety data and manipulating study results in new drug and biologics applications. The FDA has been charged with lax oversight, operating under capacity, entering into “cozy” relationships with industry, and accepting incomplete and fraudulent safety and efficacy data.

Media coverage is the public’s primary source for education about the clinical research enterprise. But

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whereas research sponsors and investigators tend to contact journalists when they are ready to announce medical breakthroughs, the media tends to focus on sensationalistic accounts of human error, concealment, fraud, and corruption. The media and the clinical research enterprise are completely misaligned in their efforts to communicate with the public.

The public and prospective volunteer communities also derive some education about the clinical research process through seeing study advertisements and promotions. Whereas less than 10% of Europeans are exposed to clinical trial promotions in the media, more than two-thirds (69%) of Americans are exposed to information on clinical research studies through television, radio, print media, and Internet advertising. Only one out of seven adult Americans is exposed to information about clinical research studies from their primary or specialty care physician, and only one out of eight Europeans learns about clinical trials from their physicians.¹²

Although the general public trusts information from healthcare providers the most, its members are not engaged as important participants in the clinical research enterprise. The medical and health professional communities are largely absent from educating the public and prospective volunteer communities. In a recent survey conducted among board-certified physicians in active community practices throughout the United States, less than half report referring their patients into clinical trials; the average referral rate for the physicians was less than one patient per year.¹³ This is primarily due to health providers lacking adequate information and context with which to make informed decisions about trials on behalf of their patients.¹⁴

Without broad understanding and context, recruitment advertising and promotional messages are met with at best passing curiosity from the public and prospective volunteers. According to recent public opinion polls, 20% of those diagnosed with severe and life-

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threatening illnesses report considering clinical trials as a healthcare option.¹² Despite a wealth of online information available today, less than 5% of the general public knows where to find information about relevant clinical trials.¹⁵ Furthermore, the public is largely unaware of where clinical research is taking place. A 2005 public poll found that 62% of Americans were unable to name a single institution, company, or organization where medical and health research is conducted.⁶

Research sponsors rarely, if ever, respond to media coverage. Government and corporate employees are usually instructed not to interact with journalists for fear of bringing more attention to a story, or of appearing defensive and self-serving. As a result, the public is largely receiving a one-sided education about the clinical trials industry in the media.

Popular culture is also unbalanced. In those rare instances when clinical research is depicted in novels and in film, it is typically portrayed as clandestine and corrupt.¹⁶ In John Le Carre's book *The Constant Gardener*, for example, a healthcare activist is murdered before she is able to expose a large pharmaceutical company that has been exploiting vulnerable African study subjects. And in the film "The Fugitive," Harrison Ford plays a physician wrongly accused for the murder of his wife. Ford is able to exonerate himself when he proves that the murder was part of a cover-up by a colleague who has been falsifying clinical research data to support a drug

for a company in which he is a major shareholder.

Closing Thoughts

Regulatory agencies and the clinical research community have responded to public confusion and distrust by implementing reforms designed to assure higher levels of compliance and reduce errors that might result in physical and ethical harm to study volunteers. Since 2001, a growing number of universities have established clinical research degree programs. European and American regulatory agencies have implemented new privacy and conflict of interest disclosure guidelines, along with new clinical trial registration requirements. Several trade associations have developed investigator certification programs. The National Institutes of Health and private sector research sponsors have launched web-based registries of clinical trial listings and results.

These reforms and measures are an important step in rebuilding the credibility of clinical research professionals, but these initiatives are insular and will be only marginally effective. They satisfy regulatory agency and research sponsor requirements to minimize potential errors, noncompliance, and fraud; they do not educate and inform the public about the clinical research process and its value in improving to public health, nor do they engender appreciation of study volunteers. Outreach and education are critically needed to engage the public as partners in, and beneficiaries of, clinical research.

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Despite widely publicized controversies that have damaged the public's trust and confidence in the credibility of stakeholders in the clinical research enterprise, the public's desire for better health and well-being has not diminished. The public has demonstrated remarkable tolerance for mistakes. There is a unique but closing window of opportunity for stakeholders in the clinical research enterprise to build collectively on this foundation in order to restore public confidence and trust.

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