

New Survey Shows Public Perception of Opportunities for Participation in Clinical Trials Has Decreased Slightly From Last Year

Fewer adults participate or plan to participate in trials for financial benefits and many of those who have ever participated rely on the advice of their regular physician

This issue of Harris Interactive *Healthcare News* focuses on public perceptions of clinical research studies. The results shown here are from a Harris Interactive survey conducted online from April 19 to 26, 2005 among a cross section of 2,261 U.S. adults aged 18 and over.

Opportunity and Participation in Clinical Research Studies

Today, one in ten (10%) adults indicate they have participated in a clinical trial, virtually unchanged since 2001(8% in 2001, 10% in 2003, 11% in 2004).

After a slight increase in the percentages of adults who say they have had the opportunity to participate in clinical trials from 2001 to 2004, opportunity to participate has fallen off slightly as 15 percent of adults today report having had the opportunity to participate in a clinical research study (compared to 19% in 2004). While the change here is very small, and could be the result of sampling or measurement error, it may also be the beginning of a new trend and leveling out of perceived opportunities for participation in clinical studies.

TABLE 1

Participated/Had Opportunity to Participate in Clinical Research Study

Base: All Adults

	2001 ¹	2003 ²	2004 ^{3*}	2005*
	%	%	%	%
Those who ever had the opportunity to participate in a clinical research study	13	16	19	15
Those who ever participated in a clinical research study	8	10	11	10

*The survey used the words "clinical research study" rather than "clinical trial" because the word "trial" has sometimes inhibited participation.

¹ 2001 data is from the "Will & Why Survey" conducted online in June 2001 by Harris Interactive among a nationwide sample of 5,348 U.S. adults aged 18 and over.

² 2003 data is from Harris Interactive Healthcare News, Volume 3, Issue 10, June 16, 2003.

³ 2004 data is from Harris Interactive Healthcare News, Volume 4, Issue 10, June 11, 2004.

Reasons for Participation

Those who have participated in clinical trials indicate a range of reasons for their participation. While these vary slightly in magnitude from year to year, the top response has continued to remain the same since 2001 –about half (51%) indicate that they participate in clinical studies to advance medicine and science.

The overall order of the reasons has retained a similar pattern; however, in 2005 there are some notable changes. There is an increase in those who indicated their doctor recommended the study as a reason they decided to participate in a clinical research study (31% now compared to 21% in 2004). Additionally there are several key decreases in both the financial benefits and education and media coverage areas:

- More than one-third (36%) of adults who participated in clinical trials said they did so to earn extra money, down from 50 percent in 2004.
- One in five (19%) participated to obtain free medication, down from 27 percent in 2004.
- Thirty percent (30%) participated to obtain education about treatment/improving their health, a decrease of nine percentage points from 2004 (39%).
- One-quarter (25%) indicated they participated in clinical studies because the information they read, saw or had heard about the study influenced them, down from 41 percent in 2004.

TABLE 2

Reasons for Participating in Clinical Research Study

“Please indicate which of the following, if any, are reasons you decided to participate in a clinical research study. Please select all that apply.”

Base: Have ever participated in a clinical research study

	2001	2003	2004	2005*
	%	%	%	%
To advance medicine/science	55	54	56	51
To obtain better treatment for my condition	56	40	44	46
To help others with the condition	47	46	45	39
To earn extra money	51	42	50	36
My doctor recommended the study	24	25	21	31
To obtain education about treatment/improving my health	33	37	39	30
I was curious about the specifics of the study	29	23	32	26
The information I read, saw, or had heard about the study influenced me	28	36	41	25
To obtain free medication	25	24	27	19
Family recommended the study	NA	NA	13	8
Friend recommended the study	NA	NA	NA*	5
I have a life-threatening illness	16	5	7	5
There were no other treatment options available	NA	NA	7	4
If I knew someone else who had the condition being studied	NA	NA	1	7
Other	NA	NA	11	6
There were no reasons in particular	NA	NA	NA	1

Note: Multiple-response question.

* Family/Friend recommended the study was a combined question in 2004.

NA = Not Asked

It appears that the draw of financial benefits attached to clinical studies may be waning for participants, and the recommendations by doctors may be a growing influence to participation. While last year the media coverage was critical to participants, this year it may be more of a liability. This may stem from recent public controversy over the potentially dangerous side effects of certain prescription drugs and, on a larger scale, more coverage of clinical studies in general and of the FDA (U.S. Food and Drug Administration). Over half of all respondents (55%) and nearly two-thirds (64%) of those who have previously participated in a clinical study believe that pharmaceutical companies’ reputations have been most affected (compared to the FDA, pharmacies, doctors, and clinical studies in general) by the recent events surrounding various prescription drugs such as Vioxx, Celebrex and Naproxen.

TABLE 3
Recent Media Coverage

“There have been recent reports of potentially dangerous side effects related to some frequently used prescription drugs, such as Vioxx, Celebrex and Naproxen. In your opinion, whose reputation has been most affected by these events?”

Base: All Adults

	All Adults	Adults Who Have Participated in a Clinical Study
	%	%
Pharmaceutical companies	55	64
The Food and Drug Administration (FDA)	26	18
Clinical studies in general	4	4
Doctors	2	3
Pharmacies	2	4
None of these	3	3
Not sure	8	4

Factors That Would Influence More People to Participate

Those who said they would consider participating in a clinical research study in the future also cite a variety of reasons. Again, the majority of the top reasons cited this year remain the same as in 2004.

Factors that are “very likely” to influence majorities of those who are considering participation in clinical research studies include:

- If I had a terminal illness (72%)
- If I thought the drug might cure me (67%)
- If there were no other medical options available to me (66%)
- If I knew there were no risks involved (61%)
- If I thought the drug/treatment would help me (61%)
- The treatment were free of charge to me (53%).

Smaller, but still substantial groups, indicated they were very likely to participate in the following scenarios:

- If my doctor recommended it (47%)
- If I received money for participating (46%)
- If I knew the risks associated with the treatment (45%)
- If I thought the drug/treatment would help someone else in the future (45%)
- If it were convenient for me to participate (43%)
- If the location were convenient for me (43%)
- If there were minimal side effects associated with the treatment (43%).

The financial connection to clinical research studies is declining as a motivation of potential new subjects, as well. While money is a factor for about half of those who would consider participating, it has fallen significantly both in terms of free treatment (53% now compared to 64% in 2004) and money for participating (46% now compared to 56% in 2004).

The primary reasons for considering participation in clinical research studies are still centered on the person themselves and their conditions and medical options.

TABLE 4
Factors Likely to Influence Decision to Participate in Clinical Research Study

“On a scale from 1-5, with 1 being “Not likely” and 5 being “Very likely”, please rate the factors below on their likeliness to influence your decision to participate in a clinical research study.”

Percent saying “5” (“very likely”)

Base: Would consider participating in a clinical research study

	2004	2005
	%	%
If I had a terminal illness	72	72
If I thought the drug might cure me	71	67
If there were no other medical options available to me	67	66
If I knew there were no risks involved	67	61
If I thought the drug/treatment would help me	57	61
If the treatment were free of charge to me	64	53
If my doctor recommended it	54	47
If I received money for participating	56	46
If I knew the risks associated with the treatment	49	45
If I thought the drug/treatment would help someone else in the future	NA	45
If it were convenient for me to participate	53	43
If the location were convenient for me	54	43
If there were minimal side effects associated with the treatment	48	43
If I knew that I would receive an active drug and not a sugar pill (placebo)	37	33
If I knew someone else who had the condition being studied	NA	30
If I had a condition other than a terminal illness	36	29
If I already take a drug/treatment made by the pharmaceutical company sponsoring the study	NA	28

NA = Not Asked

Informed Consent Process

The overwhelming majority of adults who have participated in clinical trials have very positive views of the informed consent process. Large majorities strongly agree that they understood participation was voluntary (84%) and that they were agreeing to participate in a clinical research study (83%). Three-quarters or more of participants understood what was required of them (78%); knew they could stop participating at any time (75%); and felt comfortable asking additional questions regarding the study (75%). Substantial majorities also felt secure that their confidentiality was protected (69%) and that they were made aware of both the benefits (68%) and risks (65%) to participation.

Similar to last year, most participants found the purpose of the study to be clear after reading the informed consent (85%) and agreed that their questions were generally answered by the study team regarding the informed consent process (80%).

TABLE 5
Informed Consent Process Views

“The following statements describe how well the process was explained to you when you agreed to be part of the clinical research study. Using the scale below, please indicate how strongly you agree or disagree with the statements below.”

Percent saying “strongly agree”

Base: Have ever participated in a clinical research study

	2004	2005
	%	%
I understood that participation was voluntary.	90	84
I understood that I was agreeing to participate in a clinical research study.	89	83
I fully understood what was required of me (number of visits, how long the study lasted, etc.).	81	78
I knew I could stop participating in the study at any time.	79	75
I felt comfortable asking additional questions regarding the study.	79	75
I was assured confidentiality of all personal information that I provided, with the exception of those allowed by federal law.	73	73
I felt secure that my confidentiality was protected throughout the study.	71	69
I was made aware of the benefits involved in participating in the clinical research study.	74	68
I was made aware of the risks involved in participating in the clinical research study.	74	65
I understood that I could choose other treatment options, including no treatment at all.	66	63
The informed consent document was easy to read and understand.	60	61

TABLE 6
Overview of Informed Consent Process

Base: Have ever participated in a clinical research study

	%
Said purpose of the study was “clear” after reading the informed consent	85
Agreed their questions were answered by the study team regarding the informed consent process	80
Said the study coordinator conducted the informed consent process.	54
Read the informed consent by themselves	48

Influences and Experiences of Former Participants

Participation in clinical studies appears to be a positive experience for those involved. Most of those who participated in a study would do so again, if given that chance (84%). Furthermore, a strong majority of participants (81%) describe their appointments at the study site as “not at all stressful.”

Physicians play an important role in a person’s decision to participate in a clinical research study. More than one-quarter (27%) of those who participated in a study said that their physician was their main influence in deciding to participate. Additionally, 79 percent of adults who are willing to participate in a clinical research study with an unfamiliar physician or those who are not sure indicate that they would be very or somewhat likely to check with their regular physician before participating in a clinical research study he/she is not conducting. Finally, nearly half (45%) of those who have ever participated in a clinical research study indicate that they learned everything they needed to know from the doctor/study team before deciding whether or not to participate.

TABLE 7
Sources of Influence

Base: Have ever participated in a clinical study

	%
Described their appointments at the study site as “Not at All Stressful”	81
Main influence in the decision to participate in a clinical research study:	
- No one other than myself	38
- Physician (PCP, Study Dr., Other Dr.)	27
Would be very or somewhat likely to consult with their regular physician before agreeing to participate in a clinical research study that he/she is not conducting. (Base: Those willing to participate in a clinical research study with an unfamiliar physician or those who are not sure)	79
Said “I learned everything I need to know from the physician/study team conducting the study”	45
Said “I would participate in another clinical research study”	84

Public Perceptions of Clinical Research Studies

Most adults agree that people who participate in clinical research studies are making a contribution to science (86%), are part of an experiment to test medications/treatments not already available to the public (79%), and that they learn more about their condition and health in general (76%). Smaller majorities agree that people who participate in studies have a chance to get free medicine (65%) and do not have to pay for their medical care (53%). About half of respondents agree that participants in clinical studies are taking a gamble with their health (49%) and are treated like guinea pigs (46%).

TABLE 8

Agree/Disagree With Statements About People Who Participate in Clinical Research Studies

"The following statements describe how some people feel about clinical research studies.

Using the scale below, please indicate how strongly you agree or disagree with the statements below. People who participate in clinical research studies...."

Percent saying "strongly agree" or "somewhat agree"

Base: All Adults

	%
Are making a contribution to science	86
Are part of an experiment to test medications/treatments not already available to the public	79
Learn more about their condition and health in general	76
Have a chance to get free medicine	65
Do not have to pay for their medical care	53
Are taking a gamble with their health	49
Get the best possible treatment	48
Are like guinea pigs	46
Have access to the best physicians	46
Spend a lot of time at the doctor's office	34
Are part of an experiment to test medications/treatments already available to the public	33

The public sees the greatest risks to participating in clinical studies to be possible side effects (47%) and health risks (32%) and sees the greatest benefits as helping to advance science and find a cure for diseases/conditions (36%) and helping to save lives (24%).

TABLE 9
Clinical Research Study Risks

“Which of the following do you consider to be the greatest risk of participating in a clinical research study?”

Base: All Adults

	%
Possible side effects	47
Health risks	32
Unproven therapy	9
Receiving a placebo (sugar pill)	5
Privacy concerns	2
Other	1
None; I do not believe there are any risks.	4

Note: Single-response question.

TABLE 10
Clinical Research Study Benefits

“Which of the following do you consider to be the greatest benefit of clinical research studies?”

Base: All Adults

	%
Help advance science and find a cure for diseases/conditions	36
May help to save lives	24
May help me with my condition	17
Allow medical team to find a more effective treatment	11
Monetary compensation (money) is provided	4
Allows me to help others with the condition	3
Provide information on current medications	1
Free medication is provided	1
Other	1
None; I do not believe there are any benefits.	2

Note: Single-response question.

Learn About Clinical Studies

While nearly two in five (38%) adults say the media is their main source of receiving information about clinical research studies and most (83%) understand what clinical research studies are, half (51%) of all adults indicate they would prefer to learn about clinical research studies from their regular physician.

TABLE 11
Clinical Information Obtained

Base: All Adults

	2004	2005
	%	%
Understand what is meant by “clinical research study” also known as “clinical trial”	79	83
Media (TV, radio, newspaper, magazine) main source of receiving information about clinical research studies	44	38
Would prefer to learn about clinical research opportunities from their regular/usual physician	NA	51

NA = Not Asked

Online Clinical Trial Registries

Initial reaction to online clinical trial registries is somewhat skeptical with 20 percent of adults indicating they would be not at all likely to use the service.

That said, majorities of respondents feel that all types of clinical trials should be listed in the registries (73%) and that all results, regardless of success, should be available in these registries (79%). There is mixed reaction on how to present the results with 41 percent believing the results should be in easy-to-understand layman's terms and 34 percent believing they should be in both layman's terms and scientific terms. There is also no consensus on the purpose of these registries although most ideas center on information sharing, with 40 percent saying their purpose is to promote research, 36 percent saying it is to increase awareness of clinical trials and 32 percent saying it is to share experiences of clinical trials.

TABLE 12
Online Clinical Registry Reaction

Base: All Adults

	%
Likelihood to use an online clinical trial registry:	
- Extremely, very and fairly likely (Net)	44
- Not at all likely	20
Think all types of clinical trials should be listed in the registries	73
Think all clinical trial results, regardless of success, should be available in these registries	79
Results should be presented:	
- Easy to understand layman's terms	41
- Both laymen terms and in scientific terms	34
Primary Goals of Online Clinical Trial Registries:	
- Promote Research	40
- Increase awareness of trials	36
- Share clinical trial experiences	32
- Central location tracking/reviewing study results	29
- Resource to collect feedback from general population/professionals	25

Physician/Pharmaceutical Involvement in Clinical Research

Most people (72%) believe that physician interest in finding new and better treatments is “very important” to physicians conducting clinical research. Furthermore, 59 percent rated “patients who have no other treatment alternatives” as “very important” to physicians conducting clinical research.

Fewer people believe that fame and recognition (16%), getting a scientific paper published (20%) or receiving money from drug companies (27%), are very important to physicians conducting clinical research. These patterns are consistent with 2004 results.

TABLE 13

Physician Involvement

“Please rate how important you think each of the following is to physicians conducting clinical research.”

(Percent saying “very important”)

Base: All Adults

	2004	2005
	%	%
Finding new and better treatments	80	72
Helping patients who have no other treatment alternatives	NA	59
Bringing fame and recognition to the physician’s medical center	17	16
Getting a scientific paper published	22	20
Receiving money from drug companies	29	27

NA = Not Asked

A majority of respondents (62%) rate “receiving money from drug sales” as “very important” to pharmaceutical companies conducting clinical research while more than half (57%) believe that finding new and better treatments is “very important” to pharmaceutical companies conducting research studies.

TABLE14
Pharmaceutical Involvement

“Please rate how important you think each of the following is to pharmaceutical companies conducting clinical research.”
(Percent saying “very important”)

Base: All Adults

	%
Receiving money from drug sales	62
Finding new and better treatments	57
Bringing fame and recognition to the pharmaceutical company	47
Helping patients who have no other treatment alternatives	38
Getting a scientific paper published	29

Conclusions

Overall public opinion in relation to clinical research studies appears similar to last year. However, there are a few very notable differences. There is a slight reduction in the number of adults who have had the opportunity to participate in clinical research studies. The allure of financial benefits appears to be less of a draw to both those who have participated in the past and those who are considering it in the future. For those who have participated in clinical research studies, the involvement of their physician appears to be important. Public perceptions of clinical research studies remain similar to past years and the public is still gathering most of their information from the media. The public appears skeptical to the initial introduction of online clinical trial registries for themselves, but they are open to the information sharing they could provide.

Downloadable PDFs of the Harris Interactive *Healthcare News* are available at: http://www.harrisinteractive.com/news/newsletters_healthcare.asp.

Methodology

The results published here rely on the general population data portion of the overall survey, methodology of which is explained below.

This survey was conducted online within the United States between April 19 and 26, 2005 among a nationwide cross section of 2,261 adults (aged 18 and over). Data were weighted for age, education, income, gender, race/ethnicity and region where necessary to bring them into line with their actual proportions in the population. Propensity score weighting was also used to adjust for respondents' propensity to be online.

In theory, with probability samples of this size, one could say with 95 percent certainty that the results from the total sample have a sampling error of plus or minus 3 percentage points of what they would be if the entire U.S. adult population had been polled with complete accuracy. Sampling error for the sub-samples of those who have participated in a clinical research study (261), those who would consider participating in a clinical research study (1,525), and those willing to participate in a clinical research study with an unfamiliar physician or those who are not sure (2,118) is higher and varies. Unfortunately, there are several other possible sources of error in all polls or surveys that are probably more serious than theoretical calculations of sampling error. They include refusals to be interviewed (nonresponse), question wording and question order, and weighting. It is impossible to quantify the errors that may result from these factors. These online samples were not probability samples.

These statements conform to the principles of disclosure of the National Council on Public Polls.

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