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Effects of Disclosing Financial Interests on Participation in Medical Research: A Randomized Vignette Trial

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Abstract

Background—Little is known about the effects of investigators' financial disclosures on potential research participants.

Methods—We conducted a vignette trial in which 470 participants in a telephone survey were randomly assigned to receive a hypothetical informed consent document that contained 1 of 2 financial disclosures (per capita payments to the research institution, or equity ownership by the investigator) or no disclosure. The main outcome measures were trust in medical research and willingness to participate in a hypothetical clinical trial.

Results—Participants in the equity group reported less willingness to participate than participants in the per capita payments group ($P = .01$) and the no disclosure group ($P = .03$). Trust in the investigator was highest in the per capita payments group and lowest in the equity group ($P < .001$). Trust among participants who received no disclosure was also greater than trust among participants in the equity group ($P = .04$) but did not differ significantly from trust among participants in the per capita payments group ($P = .15$). Participants in the equity group made 3 times as many negative comments as participants in the per capita payments group; and 10 participants in the equity group spontaneously said they would not participate in the hypothetical trial because of the financial interest, compared with only 1 such participant from the other groups.

Conclusions—Although investigators' financial disclosures in research do not substantially affect willingness to participate, potential research participants are more troubled by equity interests than by per capita payments.

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Financial Interests and Research Participation

There have been multiple calls for disclosing investigators' financial interests in research during the informed consent process,¹⁻³ but little is known about the effects of such disclosures. Emerging data describe the attitudes of patients who were willing to respond to an Internet survey⁴ and cancer patients already enrolled in research.⁵ However, it is unknown how the disclosure of financial interests in research affects the decision making of patients considering participation in clinical trials. In this study, we examined the effects of the disclosure of financial interests in a realistic research consent process with patients recruited as they might have been for an actual clinical trial.

Methods

We conducted a study in which we manipulated the type of financial disclosure each participant received as part of a description of a hypothetical clinical trial. Participants were a random sample of adults diagnosed with coronary artery disease. The institutional review boards of the Duke University Health System, the Johns Hopkins Medical Institutions, and Wake Forest University approved the study.

Participants and procedures

Participants were aged 18 years or older and were diagnosed with coronary artery disease (International Classification of Diseases, Ninth Revision, Clinical Modification code 414.00 or 414.01). Cardiologists in the outpatient cardiovascular medicine clinic at the Duke University Medical Center sent letters to 2840 of their patients between July 2005 and May 2006 asking them to participate in a telephone survey about financial interests in clinical research. Willing patients contacted the study team and provided oral consent to participate. To achieve the desired sample size (see Statistical Analysis), we randomly ordered the list of patients who did not respond to the letter and phoned patients down the list until enough had consented.

Participants were informed that they would be asked to read an informed consent document for a hypothetical clinical trial and would then be interviewed by telephone. Participants responded to the Trust in Medical Research measure, a 4-item measure of trust in medical researchers,⁶ to establish a baseline measure of trust. (The 4 items were as follows: "Doctors who do medical research care only about what is best for each patient"; "Medical researchers tell people everything they need to know about being in a medical research study"; "Medical researchers treat people like 'guinea pigs'"; and "I completely trust doctors who do medical research.") Participants then scheduled a follow-up telephone appointment to take place about 10 days later. In that follow-up call, a member of the study team would review the informed consent document for the hypothetical clinical trial and ask questions about the document. Enrollment lasted from August 2006 through February 2007.

During the follow-up phone call, the interviewer confirmed that the participant received and read the informed consent document for the hypothetical clinical trial. Consistent with typical practice in many clinical trials, the interviewer read a summary of each section of the informed consent document. After each section summary, the interviewer asked the participant if he or she had questions regarding that section. The interviewer then asked participants about their willingness to participate in the hypothetical clinical trial and their trust (see Measures). All interviews were audio-recorded. We used the first 40 interviews as pilot data to refine the survey measures and interview protocols.

Clinical trial scenarios

The scenarios presented in the informed consent document (Appendix A) involved a hypothetical clinical trial evaluating a new oral medication to treat coronary artery disease. The informed consent document described the potential benefits and risks of participating in the hypothetical clinical trial and, depending on random group assignment, disclosed 1 of 2 financial interests in the research involving the investigator conducting the study, or no financial disclosure whatsoever. The disclosure statements were based on previous research and input from an expert panel (Appendix B).⁷⁻⁹ The informed consent document included all required elements of informed consent, including statements of confidentiality and participants' rights.¹⁰

Each participant was randomly assigned to 1 of 3 disclosure groups: a “no disclosure” group that received no financial disclosure; a “per capita payments” group that received a disclosure indicating that the clinic received per capita payments covering the costs of the research (including the investigator's salary); and an “equity” group that received a disclosure describing an investment by the investigator in the company sponsoring the research (Appendix A). These disclosure statements were developed based on theoretical and empirical considerations discussed elsewhere.⁹ Consistent with the recommendations of the National Human Research Protections Advisory Committee¹¹ and the Association of American Medical Colleges,² both disclosure statements explained that an institutional review board and another committee had reviewed the financial interest, that these groups did not believe the interest would affect the safety or scientific quality of the clinical trial, and that more information was available upon request.

Measures

After reviewing the informed consent document, the interviewers asked participants questions developed specifically for this study regarding their likelihood of participating in the hypothetical clinical trial, the perceived importance of the financial disclosure compared to other aspects of the trial, and trust in the investigator and research institution (Appendix C). The response options for these questions used 5-point Likert scales, for which a 5 reflected the greatest endorsement or agreement (eg, response options ranging from “strongly disagree” to “strongly agree”). The questions were based on results of a focus group study and were evaluated in 10 cognitive interviews to ensure the understandability and appropriateness of the response options.¹² Finally, if participants made comments during the mock consent process, we transcribed and coded the comments using a coding scheme that we developed for this purpose. All transcripts were content-coded by 2 independent raters.

Statistical analysis

We compared demographic and clinical characteristics of the disclosure groups using χ^2 tests and Fisher exact tests for categorical variables, and 1-way analysis of variance and independent-samples *t* tests for continuous variables.

We used general linear models and follow-up *t* tests to compare the disclosure groups with respect to willingness to participate in the hypothetical clinical trial, the perceived importance of factors in the decision to participate, trust in the investigator, trust in the sponsor, and trust in the research institution. Willingness to participate was the primary outcome that motivated the sample size. We assumed that a minimally policy-relevant difference would be in the range of 0.30 to 0.40 SDs or greater. With a 2-tailed alpha level of 0.05 and 80% statistical power, we required 100 participants per group to detect differences of at least 0.40 SDs. To support the exploratory multivariable modeling described below, we increased this number to 150 patients per group.

We expected that the baseline Trust in Medical Research score, measured during the screening interview, would moderate the effect of disclosure on the outcomes and/or serve as a useful covariate to create a more powerful test of differences between the disclosure groups. Thus, in addition to disclosure group, we included the baseline Trust in Medical Research score and the interaction of disclosure group by Trust in Medical Research score as factors in the general linear models. The Trust in Medical Research score did not interact with any of the outcomes, so we present only the main effects of the score in terms of semipartial correlations. A semipartial correlation reflects an association between the Trust in Medical Research score and the outcome after adjustment for differences due to disclosure group assignment.

We also examined whether patient characteristics moderated the effect of disclosure by testing the joint significance of all 2-way interactions between each patient characteristic and disclosure group. This omnibus test was not significant, so no results are presented. We compared trust in the investigator, the research institution, and the sponsoring company within person using a repeated measures analysis of variance. Finally, we summarized the frequency and nature of spontaneous comments related to the investigator's financial interest, which we coded as "positive," "negative," and "refusal to participate." We used χ^2 tests with exact *P* values to compare the frequency of these comments by disclosure group.

Results

Participant characteristics

Figure 1 displays the recruitment status based on the 2840 letters that were sent to patients. Follow-up phone contact, initiated by either the patients or research staff, was made for 1545 of the patients to reach the goal of 500 patient interviews. Of the patients we phoned, 510 agreed and completed interviews, whereas 862 decliners or passive decliners (ie, did not return 4 phone calls). After we excluded the 40 patients who participated in the pilot phase of the study, 470 surveys were available for the analysis. Table 1 shows the characteristics of the patients by disclosure group. None of the participant characteristics differed by experimental group ($P > .19$ for all comparisons). Most participants were white men with relatively high education levels and incomes. One third of the participants had previously participated in a research study, half of whom had participated in a cardiology trial.

Effects of disclosure on willingness to participate

Table 2 displays the mean responses by experimental group for each of the outcomes. Although patients in all 3 disclosure groups expressed a moderate willingness to participate in the hypothetical clinical trial, there were significant differences across groups ($P = .02$). Patients in the equity group reported less willingness to participate (mean, 3.20; SD, 1.32) than patients in the per capita payments group (mean, 3.51; SD, 1.30; $P = .01$) and the no disclosure group (mean, 3.50; SD, 1.29; $P = .03$). This difference corresponded to an effect size of 0.23 standard deviations. Patients with higher Trust in Medical Research scores (measured at baseline) expressed greater willingness to enroll in the hypothetical clinical trial (semipartial $r = 0.22$; $P < .001$).

Participants placed less importance on the possibility of financial benefit to the investigator than on other factors (Table 2). Patients in the equity group rated the possibility of financial benefit as more important (mean, 2.65; SD, 1.59) than did patients in the per capita payments group (mean, 1.97; SD, 1.24; $P < .001$), corresponding to a difference of 0.49 SDs. Helping others was rated as somewhat more important in the per capita payments group (mean, 4.14; SD, 0.95) than in the no disclosure group (mean, 3.87; SD, 1.01; $P = .01$), corresponding to a difference of 0.28 SDs. No other importance factors differed by

disclosure group. The only importance factor related to the Trust in Medical Research score was the importance of helping others (semipartial $r = 0.18$; $P < .001$).

Effects of disclosure on trust

Trust in the hypothetical investigator was moderately high among all 3 disclosure groups and differed by group. Level of trust in the investigator was highest in the per capita payments group (mean, 3.88; SD, 0.82) and lowest in the equity group (mean, 3.60; SD, 1.01; $P < .001$), corresponding to a difference of 0.30 SDs. Trust in the investigator was also greater in the no disclosure group (mean, 3.77; SD, 0.82) than in the equity group ($P = .04$; difference, 0.18 SDs), but did not differ significantly from the per capita payments group ($P = .15$, difference, 0.13 SDs). Higher Trust in Medical Research scores (measured at baseline) were associated with greater trust in the investigator at the time of consent (semipartial $r = 0.38$; $P < .001$).

Trust in the hypothetical sponsor and research institution did not differ by disclosure group. However, Trust in Medical Research scores were positively associated with both trust in the sponsor (semipartial $r = 0.35$; $P < .001$) and trust in the research institution (semipartial $r = 0.37$; $P < .001$). As shown in Table 2, trust was highest for the research institution, next highest for the investigator, and lowest for the research sponsor ($P < .001$). (There was a significant interaction between object of trust and disclosure group [$P = .04$], but the main effect for object of trust remained significant for each disclosure group.)

Participants' comments about financial interests

Table 3 shows the distribution of participants' comments about the hypothetical investigator's financial interests. Few patients (less than 3%) had positive comments, and these comments did not differ significantly between the disclosure groups. Positive comments in the per capita payments group included, "OK, that sounds more appropriate. So there's no direct payment to him, but through the university. OK, I'm good..." and "I think those statements there are very important." Positive comments in the equity group referred to the investigator's financial interest as a motivation for doing a good job (eg, "It looks like he'd have this real incentive for this thing to go real well, and I guess that's all to the good.").

There were 3 times as many clearly negative comments in the equity group as in the per capita payments group. In the per capita payments group, negative comments included the idea that the investigator might act inappropriately to secure future funding from the sponsor, and a more general suspicion of connections between pharmaceutical companies and physicians or investigators. In the equity group, the negative comments indicated discomfort with the possibility that the investigator might influence the results of the study to realize personal financial benefit, and doubts about the ability of the institutional review board to know the risks posed by the financial interest. Stronger language was used in the equity group than in the per capita payments group, including such terms as "disingenuous," "unacceptable," and "unethical."

Eleven patients spontaneously reported that they would not participate in the hypothetical clinical trial because of the financial interest, and all but 1 of these patients were in the equity group.

Discussion

Our study examined the role of randomly assigned financial disclosures in a realistic clinical trial consent process, using a broader array of outcomes than in earlier studies. Although the results confirm some findings of previous research, they provide additional insights into the

effects of the disclosure of financial interests in research that have important implications for policy.

Effect of disclosure on the consent process

The findings document how disclosures of financial interests in research affect discussions with patients during the consent process. Potential research participants expressed few concerns about per capita payments, but almost a quarter of patients in the equity group were bothered by the financial interest. This finding, along with earlier qualitative research with patients and investigators,^{7,13} suggests that policy makers should consider more restrictive policies for equity relationships than for other financial interests. We also found a minority of patients who viewed equity interests positively (eg, believing that the equity interest provided an incentive for the investigator to do good work, or that the equity interest indicated that the investigator believed the experimental product was safe and effective). Such data highlight the need to craft policies that are sensitive to the full range of effects that disclosures may have on potential research participants.

Effect of disclosure on trust

It is striking that, at a time when there are multiple allegations of the lack of trustworthiness of the pharmaceutical industry,^{14,15} disclosure had a small effect on trust in the investigator and no effect on trust in the research sponsor. The greater determinant of trust in the investigator, sponsor, and research institution was patients' trust in medical research prior to the consent process. More research is needed to understand factors that promote or discourage the public's trust in medical research.

Role of financial disclosures in decisions to enroll in research

We found that disclosing an investigator's financial interest did not substantially affect participants' decisions to enroll in a hypothetical clinical trial. At the same time, we found that participants attached different levels of importance to different types of financial interests. The perceived importance of the financial disclosure was much greater for investigator equity ownership than for per capita payments and no disclosure. The difference suggests that patients value some disclosures even when the information does not greatly affect their decisions. This finding underscores the importance of clarifying the goal of disclosure. If the goal is to provide information that affects decisions to participate, one could argue on the basis of our findings that disclosures are not very meaningful to most people asked to participate in research. However, the data presented here, along with prior work,^{4,7} suggest that some disclosures address patients' "right to know"—that is, their interest in learning about financial relationships regardless of whether this knowledge will affect their participation.

Limitations

In interpreting the results of this study, it is important to recognize that the demographic characteristics of the sample, albeit predominantly composed of well-educated white men, resemble enrollment data from cardiology trials conducted at the clinic where we recruited patients (personal communication, C. McNeil, May 29, 2007). This provides some assurance that the results generalize to real clinical trial populations in this therapeutic area. At the same time, however, we were limited in our ability to examine sociodemographic variables, such as race/ethnicity, that have been associated with trust in research. There was also a fairly low response rate, which is also consistent with clinical trial enrollment rates. It is unclear how patients who declined to participate in the study would view the financial disclosures. Furthermore, although we simulated the consent process for clinical trials, participants' decisions to participate were hypothetical. It would be pragmatically impossible

to conduct such a study in an actual clinical setting without deception, because financial interests of investigators could not be randomly assigned. Despite such limitations, our study had reasonable verisimilitude.

Conclusion

Although disclosure of investigators' financial interests in research does not substantially affect willingness to participate, potential research participants attach some importance to this information, and they are more troubled by equity interests than by per capita payments that cover the costs of research. A far greater determinant of willingness to participate appears to be people's trust in medical research and researchers.

Acknowledgments

Members of the expert advisory committee provided useful suggestions regarding the design of the study. We thank the cardiologists at the Duke University outpatient cardiovascular medicine clinic for assistance with participant recruitment; and Damon Seils of Duke University for editorial assistance and manuscript preparation. Mr Seils did not receive compensation for his assistance apart from his employment at the institution where the study was conducted.

Funding/Support

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Appendix A

Mock Informed Consent Document

Project Name: Testing Corvasflo in Patients with Coronary Artery Disease

Principal Investigator: Dr. Pat Smith, MD

Telephone number: (111) 111-1111

Introduction

You are being asked to join this clinical research study because you have been diagnosed with coronary artery disease (CAD). CAD is a condition in which the blood vessels that supply the heart with blood are narrowed, making people more likely to have chest pain when they exercise, and more likely to have a heart attack. Corvasflo is an oral drug designed to help people with CAD. The results from research done with a small number of people indicate that Corvasflo is well-tolerated. However, Corvasflo has not been studied in any large research studies. Because it appears to be a promising new drug that may help people with CAD, we are studying Corvasflo in a large number of people like you.

This study is being conducted by Dr. Pat Smith at University Medical Center (UMC) and is funded by First Rate Pharmaceuticals

Purpose of the Study

The main purpose of this study is to evaluate how safe and effective Corvasflo is in treating CAD. The specific purpose of this study is to see if Corvasflo delays the time until persons with CAD have a heart attack. The study will also see if Corvasflo reduces the likelihood of having chest pain or other heart problems.

How the Study Works

During the study, you will continue to take all of your current medications. In addition, you will be given either the active study drug (Corvascflo) or an inactive drug called placebo. Whether you get inactive placebo or active study drug is decided by chance (like flipping a coin) and neither you nor your doctor will know whether you are taking Corvascflo or placebo. While you are in the study, you will take 2 tablets of the study drug by mouth (active study drug or inactive placebo) twice a day (morning and evening) in addition to your other regular medications. You will do this for six months. If you should suffer from any side effects, the dose of study drug may be reduced or stopped. In case of medical emergency, the information regarding the study drug you are taking (active study drug or inactive placebo) will be readily available to your doctor. We will ask you to visit your study site regularly for checkups on your overall health.

Risks to You

Corvascflo can have side effects even when used as directed. These side effects may occur at the dose of Corvascflo that is used in this study. Some patients taking Corvascflo were found to have abnormal liver function tests (indicating liver injury) and anemia (low amount of red blood cells). While you receive Corvascflo or placebo, a doctor will arrange for you to have regular blood tests to check for changes in your liver function and hemoglobin level. If you notice yellowing of the skin or eyes (jaundice), or if you have fever with vomiting or nausea, see a doctor at once because this may be related to abnormal liver function. Headache was the most common side effect of Corvascflo in early clinical studies. You may also notice one or more of the following side effects: flushed appearance, inflammation of the throat and nasal passages, low blood pressure, palpitations (feeling your heart beating), heartburn, tiredness, itching, or nausea. Other less common side effects that you might notice include: vomiting, abdominal pain, diarrhea, or skin rash. If you notice any other side effects or signs of allergic reaction (such as swelling of the face or tongue, rash, itching) while you are taking Corvascflo, or if any of the side effects mentioned above worry you, please inform your study doctor promptly. If you feel dizzy while taking Corvascflo, do not drive or operate any tools or machines. It is possible that complications and side effects of the study drug, which are still unknown at this time, may occur. You will be informed about any new findings related to Corvascflo.

Benefits to You

There is no guarantee that you will benefit directly from this research. You would not be expected to benefit directly from receiving placebo. First Rate Pharmaceuticals will provide Corvascflo or placebo free of charge to participating research subjects. Information obtained during the course of this clinical research study may contribute to a better understanding of your disease and may be useful in selecting medicines for your future treatment. Regardless of any individual benefit, the knowledge gained from this study may contribute to information that would allow the use of this drug or similar drugs in later treatment for you and other people with CAD.

Alternatives to Study Participation

You do not need to participate in this study to receive care for your CAD. You may continue to receive your current medications or receive other medications approved by the Food and Drug Administration (FDA). Or you may be eligible to participate in another research study.

Compensation

You will not be paid for your participation in this research study. The study drug, the visits, and all the laboratory tests related to the study will be provided free of charge.

Financial Disclosure [This section does not appear in the no disclosure group] Dr. Smith, the doctor who is responsible for the study, is being paid by First Rate Pharmaceuticals to conduct this study. Dr. Smith will benefit financially from this study, as described in more detail below.

[Per capita payment group: “First Rate Pharmaceuticals pays the hospital/clinic running this research study for study supplies, a portion of Dr. Smith's regular salary, staff salaries, and for each person who agrees to participate in the study. This amount of money is just enough to cover the cost of running the study.”]

[Equity group: “This research study is designed to test a product made by First Rate Pharmaceuticals. The person running this study has an investment in First Rate Pharmaceuticals, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that the person running this study could gain or lose money depending on the results of this study.”]

The Institutional Review Board and a committee at University Medical Center have reviewed the possibility of financial benefit. They believe that the possible financial benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Confidentiality

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of University Medical Center (UMC). For records disclosed outside of UMC, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Smith's office.

If you choose to be in this study, the study doctor will get personal information from you. This may include information that might identify you. This information may include:

- Medical and Research Records
- Records about phone calls
- Records about your study visits
- Records of physical exams
- Laboratory, x-ray, and other test results
- Records about study drugs

In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of First Rate Pharmaceuticals, FDA or the University Medical Center Institutional Review Board. If any of these groups review your research record, they may also need to review your entire medical record.

If you give permission for your identifiable health information to be given to a person or business other than one of those covered under the federal Privacy Rule, the information may no longer be protected by this rule (the Health Insurance Portability and Accountability Act). There is also a risk that your information will be released to others without your permission. Confidentiality of your records will be maintained to the greatest extent possible. However the Health Authorities such as the FDA, the Monitors and other study

personnel representing the Sponsor, the Institutional Review Boards, Ethics Committees and regulatory authorities (such as FDA) and your health insurance company may need and will be granted direct access to your medical records to verify either the clinical research procedures or the data they contain. By signing this consent form you are giving your authorization to such access.

Your permission to use and disclose your health information will not expire. You may revoke your permission at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study. You have the right to review and copy your health information. However, if you decide to be in this study and sign this consent form, you will not be allowed to look at or copy your health information until after the research study is completed.

The information obtained from this study, including the results of all tests upon yourself, will be held in both computerized and manual filing systems, although these will not identify you by name. These records may be used for product registration purposes and thus made available to Health Authorities worldwide, and they may be sent abroad, for example to Europe, for processing by either company personnel or a third party. These records will only be kept for as long as necessary and during that time will be kept confidential and, to the extent permitted by applicable laws and regulations, will not be made publicly available. If the results of this research study are published, your identity will remain confidential. Any identifying information (such as your name or address) will be removed from all records before they are released to the Sponsor. You will not be identified personally in any presentation or report dealing with this research.

The study results will be retained in your research record for at least six years or until after the study is completed, whichever is longer. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at UMC. Any research information in your medical record will be kept indefinitely.

Your Rights

1. It is necessary that you read several general points that apply to everyone who takes part in this study:
2. You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study Sponsor. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at UMC. If you do decide to withdraw, we ask that you contact Dr. Smith in writing and let him know that you are withdrawing from the study. Dr. Smith's mailing address is 1000 Medical Street, Nowhere USA.
3. You will not be charged (billed) for taking part in this study.
4. Your name will not be used in medical journal articles or at meetings when the results of this study are reported.
5. Immediate necessary medical care is available at University Medical Center in the event that you are injured as a result of your participation in this research study.

However, there is no commitment by University Medical Center or your study doctor to provide monetary compensation or free medical care to you in the event of a study-related injury. Further information concerning this and your rights as a research subject can be obtained from the University Medical Center Institutional Review Board (IRB) Office at (111) 111-1111.

6. You will be given a signed copy of this consent form and a signed copy will be placed in the study files.

Authorization

I have read and had explained to me the purpose of the study as well as the potential benefits and risks of participation in the study. I have had the opportunity to ask questions and my questions have been answered. I hereby give my consent to be a participant in this study. I have been told about the potential adverse reactions that could be caused by Corvascfo. I am aware that I will receive a copy of this signed consent form.

I have been told that, by signing this consent form, I authorize access to my medical records to the Monitor(s) and the Auditor(s) representing the Sponsor, and if needed to members of the Institutional Review Board/Ethics Committee or regulatory authorities such as the FDA, for verification of clinical research procedures and/or data.

I also have been told that the information obtained from this study, including the results of all tests upon myself, will be held in both computerized and manual filing systems, although these will not identify me by name. These records may be used for product registration purposes and thus may be made available to Health Authorities worldwide, and they may be sent abroad for processing by either company personnel or a third party.

[This sentence not in the no disclosure informed consent document] I understand that Dr. Smith may benefit financially from conducting this study.

I understand that I am free to withdraw from the study:

- at any time
- without having to give a reason for withdrawing
- and without affecting my future medical care

Signature of Subject

Date

Signature of Person Obtaining Consent

Date

Appendix B

The members of the expert panel were Mark Barnes (Ropes & Gray), Rebecca Coleman (Theravance, Inc), Joseph DiCesare (Novartis), John M. Falletta (Duke University), Robert A. Gatter (Pennsylvania State University), Julie Gottlieb (The Johns Hopkins University), Jeffrey Kahn (University of Minnesota), Mary Faith Marshall (University of Minnesota), S. Van McCrary (State University of New York at Stony Brook), Erica Rose (GlaxoSmithKline), and Michael B. Waitzkin (FoxKiser).

Appendix C

Questions used to measure outcomes (all interviewer-administered)

Question	Response Options
If we asked right now, how likely would you be to agree to participate in this clinical research study?	<p>1 I definitely would not participate.</p> <p>2 I probably would not participate.</p> <p>3 I am uncertain if I would or would not participate.</p> <p>4 I probably would participate.</p> <p>5 I definitely would participate.</p>
How important are the <u>possible health benefits</u> to you in deciding if you would want to participate.	1 Not at all important
How important are the <u>possible health risks</u> to you in deciding if you would want to participate.	2 Somewhat important
How important is the <u>convenience of participating</u> in deciding if you would want to participate.	3 Important
How important is the <u>possibility that Dr. Smith might benefit financially</u> from this medical research study in deciding if you would want to participate	4 Very important
How important is the <u>possibility of helping other patients in the future</u> in deciding if you would want to participate.	5 Extremely important
I completely trust Dr. Smith to do good medical research.	1 Strongly Disagree
I completely trust University Medical Center to do good medical research.	2 Disagree
I completely trust First Rate Pharmaceuticals, the company that is funding this research study.	3 Neutral
	4 Agree
	5 Strongly Agree

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Figure 1.
Recruitment Flow Diagram

Table 1**Participant Characteristics**

Characteristic	All Participants (N = 470)	Disclosure Type		
		No Disclosure (N = 141)	Per Capita Payments (N = 160)	Equity (N = 169)
Male, n (%)	347 (73.8)	101 (71.6)	116 (72.5)	130 (76.9)
Age, mean (SD), y	66.9 (11.1)	67.1 (11.6)	66.7 (11.5)	66.8 (10.4)
Race/ethnicity, n (%)				
Black	30 (6.4)	9 (6.4)	13 (8.1)	8 (4.7)
Hispanic	6 (1.3)	2 (1.4)	1 (0.6)	3 (1.8)
White	426 (90.6)	129 (91.5)	143 (89.4)	154 (91.1)
Other	7 (1.5)	3 (2.1)	0	4 (2.4)
No answer	1 (0.2)	0	1 (0.6)	0
Education level, n (%)				
Grade 8 or lower	6 (1.3)	3 (2.1)	1 (0.6)	2 (1.2)
Some high school	25 (5.3)	5 (3.6)	4 (2.5)	16 (9.5)
High school diploma or equivalent	73 (15.5)	21 (14.9)	28 (17.5)	24 (14.2)
Business, technical, or vocational school after high school	13 (2.8)	2 (1.4)	5 (3.1)	6 (3.6)
Some college	84 (17.9)	27 (19.2)	37 (23.1)	20 (11.8)
Two-year college or associate's degree	28 (6.0)	7 (5.0)	11 (6.9)	10 (5.9)
Four-year college degree	99 (21.1)	34 (24.1)	31 (19.4)	34 (20.1)
Some graduate or professional school	18 (3.8)	4 (2.8)	7 (4.4)	7 (4.1)
Graduate or professional degree	123 (26.2)	37 (26.2)	36 (22.5)	50 (29.6)
Don't know	1 (0.2)	1 (0.7)	0	0
Annual household income, n (%)				
< \$15 000	28 (6.0)	10 (7.1)	6 (3.8)	12 (7.1)
\$15 000-\$29 999	53 (11.3)	16 (11.4)	21 (13.1)	16 (9.5)
\$30 000-\$44 999	60 (12.8)	16 (11.4)	23 (14.4)	21 (12.4)
\$45 000-\$59 999	59 (12.6)	20 (14.2)	18 (11.3)	21 (12.4)
\$60 000-\$99 999	124 (26.4)	42 (29.8)	45 (28.1)	37 (21.9)
> \$100000	106 (22.6)	29 (20.6)	31 (19.4)	46 (27.2)
Don't know/unsure	15 (3.2)	5 (3.6)	4 (2.5)	6 (3.6)
No answer	25 (5.3)	3 (2.1)	12 (7.5)	10 (5.9)
Ever been in a research study, n (%)				
Yes	157 (33.4)	46 (32.6)	56 (35.0)	55 (32.5)
No	306 (65.1)	94 (66.7)	101 (63.1)	111 (65.7)
Unsure	7 (1.5)	1 (0.7)	3 (1.9)	3 (1.8)
Previous study was heart-related, n (%)				
Yes	86 (54.8)	23 (50.0)	30 (53.6)	33 (60.0)
No	67 (42.7)	22 (47.8)	25 (44.6)	20 (36.4)
Unsure	4 (2.5)	1 (2.2)	1 (1.8)	2 (3.6)

Table 2
Responses by Experimental Group and Relationship With Trust in Medical Research

Outcome	Disclosure Type			P Value *	Semipartial $r^{\dagger}$
	No Disclosure (n = 141)	Per Capita Payments (n = 160)	Equity (n = 169)		
Willingness to participate	3.50 (1.29)	3.51 (1.30)	3.20 (1.32)	.02	0.22
Importance for decision					
Potential financial benefit for investigator [‡]	—	1.97 (1.24)	2.65 (1.59)	<.001 [§]	
Health benefit	3.59 (1.18)	3.59 (1.09)	3.56 (1.07)	.93	
Health risk	3.67 (1.16)	3.75 (1.17)	3.65 (1.15)	.80	
Convenience	3.10 (1.10)	3.02 (1.13)	2.98 (1.15)	.63	
Helping others	3.87 (1.01)	4.14 (0.95)	4.01 (1.02)	.04	0.18
Trust in investigator	3.77 (0.82)	3.88 (0.82)	3.60 (1.01)	.001	0.38
Trust in research sponsor	3.14 (0.95)	3.19 (0.86)	3.07 (1.08)	.21	0.35
Trust in research institution	4.01 (0.80)	4.14 (0.76)	4.05 (0.85)	.15	0.37

* P values are from a general linear model that included the Trust in Medical Research score as a covariate.

[†] Values are semipartial correlations between the outcome variable and the Trust in Medical Research score, with adjustment for differences by disclosure group.

[‡] Participants in the no disclosure group were not asked about the importance of potential financial benefit.

[§] P value is from an independent-samples *t* test.

Table 3

Reactions to the Possibility of Financial Benefit by Disclosure Group

Remark	Disclosure Type			Exact <i>P</i> Value*
	None (n = 141)	Per capita payments (n = 160)	Equity (n = 169)	
Clearly positive	0	3 (1.9)	4 (2.4)	.23
Clearly negative	0	10 (6.3)	32 (18.9)	< .001
Refuse to participate	2 (1.4)	1 (0.6)	9 (5.3)	.01