Participants' perception of pharmaceutical clinical research: a cross-sectional controlled study

Gerardo González-Saldivar¹
René Rodríguez-Gutiérrez²
José Luis Viramontes-Madrid³
Alejandro Salcido-Montenegro²
Kevin Erick Gabriel Carlos-Reyna²
Andrés Marcelo Treviño-Alvarez²
Neri Alejandro Álvarez-Villalobos⁴
José Gerardo González-González²

¹Ophthalmology Department,

²Endocrinology Division, Hospital Universitario "Dr. José E. González", Facultad de Medicina, Universidad Autónoma de Nuevo León, Monterrey, Nuevo León, ³Instituto Nacional de Salud Pública, Cuernavaca, Morelos, ⁴Medical Statistics Department, Hospital Universitario "Dr. José E. González", Facultad de Medicina, Universidad Autónoma de Nuevo León, Monterrey, Nuevo León, Mexico

Background: There is scarce scientific information assessing participants' perception of pharmaceutical research in developed and developing countries concerning the risks, safety, and purpose of clinical trials.

Methods: To assess the perception that 604 trial participants (cases) and 604 nonparticipants (controls) of pharmaceutical clinical trials have about pharmaceutical clinical research, we surveyed participants with one of four chronic diseases from 12 research sites throughout Mexico.

Results: Participation in clinical trials positively influences the perception of pharmaceutical clinical research. More cases (65.4%) than controls (50.7%) perceived that the main purpose of pharmaceutical research is to cure more diseases and to do so more effectively. In addition, more cases considered that there are significant benefits when participating in a research study, such as excellent medical care and extra free services, with this being the most important motivation to participate for both groups (cases 52%, controls 54.5%). We also found a sense of trust in their physicians to deal with adverse events, and the perception that clinical research is a benefit to their health, rather than a risk. More controls believed that clinical trial participants' health is put at risk (57% vs 33.3%). More cases (99.2%) than controls (77.5%) would recommend participating in a clinical trial, and 90% of cases would enroll in a clinical trial again.

Conclusion: Participation in clinical trials positively influences the perception that participants have about pharmaceutical clinical research when compared to nonparticipants. This information needs to be conveyed to clinicians, public health authorities, and general population to overcome misconceptions.

Keywords: perceptions, clinical trials, chronic disorders, participants' perception, pharmaceutical industry, developing countries

Introduction

During the past 3 decades, pharmaceutical clinical trials have intensively increased worldwide, significantly expanding into developing countries.¹⁻³ In the last 5 years, registration of research conducted in Latin America in the [ClinicalTrials.gov](https://clinicaltrials.gov) registry has increased from 4,499 to 11,100.⁴

As a consequence of ethical misconduct by some researchers, both the international clinical research regulations and the concern of providing appropriate protection to clinical research participants have grown intensively.^{5,6} Unfortunately, a lack of audits or inspections in many clinical research sites all over the world is evident.^{1,3,7} Certification by well-known associations focusing on the protection of participants is now highly recommended by public health agencies.⁸ Despite these efforts to ensure ethical behavior regarding participant protection in clinical research, there is still very limited information regarding the participants' perception of the risks, safety, and

Correspondence: José Gerardo González-González
Endocrinology Division, Hospital Universitario "Dr. José E. González," Facultad de Medicina, Universidad Autónoma de Nuevo León, Ave Madero y Gonzalitos s/n, Col Mitras Centro, CP 64460 Monterrey, Nuevo León, Mexico
Tel/fax +52 81 8348 3220
Email jgerardo@meduanl.com

purpose of clinical trials.^{9–13} Recent efforts have been made to approach clinical research participants and assess their perception and experiences with tools such as the Research Participant Perception Survey and organizations such as the Patient-Centered Outcomes Research Institute.^{11,13–16} Nevertheless, these efforts still focus on developed countries and clinical research sites with certified clinical practice excellence. Comparing the perceptions of participants from the USA and the rural and urban People's Republic of China yielded different reasons and concerns about participating in clinical research.¹⁷ A scientific examination of this issue may generate critical feedback that could improve the execution of clinical trials.

We conducted a cross-sectional, controlled, multicenter survey in various academic and nonacademic pharmaceutical clinical research sites. The primary end point was to assess participant's perception (ie, regard and understanding) of clinical research trials in a large population with one of four highly prevalent chronic diseases: type 2 diabetes, hypertension, chronic obstructive pulmonary disease, and rheumatoid arthritis. The secondary end point was to compare their perceptions by sex, age, and disease to determine whether they were influenced by the inherent characteristics of the participant categories classified by these variables.

Methods

Study participants

Ethics approval was obtained from Comité de Ética en Investigación de la Facultad de Medicina y Hospital Universitario de la Universidad Autónoma de Nuevo León. From September 2013 to March 2014, research sites consecutively enrolled patients who met all eligibility criteria. Cases were males and females, aged 18–80 years, who had lived in Mexico for at least 10 years, who had participated or were currently participating in Phase II or III pharmaceutical industry-funded clinical trials, and who had attended at least their sixth visit. Trial participants (cases) were recruited in equally proportionate populations among each of the four chronic degenerative disorders evaluated (type 2 diabetes, hypertension, chronic obstructive pulmonary disease, and rheumatoid arthritis). In the eventuality of studied comorbidities, the disease of interest in their clinical trial determined the assignment into our study disease groups. These four chronic diseases were chosen because of their high prevalence and the high number of approved treatments already available and because they have a low short-term risk of death or serious complications. Cases were paired (correspondingly distributed by disease) with controls, who had never participated

in, or been invited to participate in, a clinical trial and who had visited the primary care and specialty outpatient clinics for reasons other than trials. Recruitment took place in 12 clinical research sites throughout Mexico. All participants provided written informed consent and were able to complete the self-survey.

Clinical research sites

All the research sites had participated in pharmaceutical research (in >45 clinical trials), for at least 10 years, and had a professional pharmaceutical research team; nine out of the 12 sites had sections within their facilities designated for conducting clinical trials. All sites also provided primary care and specialty outpatient services to the general population.

Study protocol

Cases were invited to participate while attending their research study site and controls while at their specialty outpatient clinics. In all cases, a staff member, unrelated to the trial the patient was enrolled in, acquired the patient's demographic data and explained the survey. Any questions from participants were clarified by the research site staff in charge of the surveys. Once finished, the evaluator reviewed whether the survey was correctly completed. After completion, all surveys were sent back to a central site for data management.

Procedures

The survey was developed by two of the authors (JGGG and JLVM) with >15 years of experience in original and pharmaceutical clinical research, based on their experience in day-to-day clinical research activities. A two-phase prepilot study and a pilot study were performed to validate the survey. First, the original draft was tested in two focus groups, each with seven to eight participants (80% previously involved in a clinical research study). Then, two individual semistructured interviews were randomly chosen to be used in six out of the 12 sites (12 interviews in total). Key points mentioned by the participants in each stage were used to revise the questions and their order of appearance in the survey. After this, a final questionnaire was formulated and piloted in a total of 30 individuals who had the same eligibility criteria as the ones included in this study. Minor inconsistencies were found and taken into account to draft the survey used in this study (Supplementary material). All surveys were completed with paper and pencil.

One hundred surveys were sent to each research site: 50 for cases and 50 for controls. In all research sites, the staff member responsible for survey application received a careful explanation about the procedure and possible questions that

could arise during the evaluation. We analyzed 17 multiple-choice questions: each with two to eight choices. Both cases and controls were surveyed with the same questions in addition to a unique question specifically designed for each group. Data presented in this article are a fraction of the whole survey, given that it assessed diverse subtopics regarding participants' perception of clinical research. This study focused on the general perception and motives for participation in pharmaceutical clinical research.

Statistical analysis

All results are reported as mean $\pm$ SD unless otherwise stated. A P -value ≤ 0.05 was statistically significant. Descriptive statistics were used for quantitative variables, measures of central tendency, and dispersion. In the case of qualitative variables, frequencies were obtained. In quantitative comparative data, we used an unpaired Student's t -test. The response differences between groups were studied using Pearson's χ^2 test or Fisher's exact test for 2×2 tables. The statistical analysis was performed using IBM SPSS Statistics 20.0 (IBM Corporation, Armonk, NY, USA).

Results

Study population

Demographic and clinical characteristics of the study population are shown in Table 1. A total of 1,208 participants

were included: 604 cases and an equal number of controls. All participants approached agreed to be included. Two-thirds of the cases (65.4%) were participating in pharmaceutical research for the first time. Cases were significantly older than controls (54.8 ± 13.9 years vs 47.0 ± 15.5 years, $P < 0.05$). Two-thirds of cases and controls were female. More than one-third of the whole study population had at least 9 years of education, and $>75\%$ had access to social or private health insurance.

Perception of pharmaceutical clinical research

The most and least common responses are shown in Table 2. Unless otherwise stated, statistical analysis by sex, age, and disease category was not different from the results found in the statistics as a whole group.

To cure more diseases and to do so more effectively were considered the main reasons for pharmaceutical companies to conduct clinical trials (cases 65.4%; controls 50.7%). More cases (98.8%) than controls (81.3%) believed that it is correct to perform research on humans. Controls considered trials as a business (4.3%), more so than cases (0.5%), and were more likely to believe that its risks outweigh the benefits (controls 12.1% vs cases 1.2%).

More cases felt protected in case of a serious adverse event related to the experimental drugs (93.4%) compared

Table 1 Demographic and clinical characteristics of the study population

Characteristic	Study population		DM2		COPD		RA		HT	
	Cases (n=604)	Controls (n=604)	Cases (n=151)	Controls (n=151)	Cases (n=151)	Controls (n=151)	Cases (n=151)	Controls (n=151)	Cases (n=151)	Controls (n=151)
Age, mean $\pm$ SD (years)	54.9 $\pm$ 13.9	47.1 $\pm$ 15.5*	52.2 $\pm$ 12.8	46.6 $\pm$ 15.7*	60.3 $\pm$ 14.2	53.1 $\pm$ 16.7*	50.1 $\pm$ 13.4	41.6 $\pm$ 15.3*	56.8 $\pm$ 13.1	47 $\pm$ 12.1*
Age group, n (%)										
<50 years	216 (35.8)	320 (53.0)*	68 (45.0)	83 (55.0)	31 (20.5)	57 (37.7)*	71 (47.0)	103 (68.2)*	46 (30.5)	77 (51.0)*
≥ 50 years	388 (64.2)	284 (47.0)	83 (55.0)	68 (45.0)	120 (79.5)	94 (62.3)	80 (53.0)	48 (31.8)	105 (69.5)	74 (49.0)
Sex, n (%)										
Female	377 (62.4)	394 (65.2)	101 (66.9)	95 (62.9)	69 (45.7)	92 (60.9)**	126 (83.4)	110 (72.8)**	81 (53.6)	97 (64.2)
Male	227 (37.6)	210 (34.8)	50 (33.1)	56 (37.1)	82 (54.3)	59 (39.1)	25 (16.6)	41 (27.2)	70 (46.4)	54 (35.8)
Years of education, n (%)										
<9 years	363 (60.1)	341 (56.5)	90 (59.6)	82 (54.3)	89 (58.9)	76 (50.3)	90 (59.6)	85 (56.3)	94 (62.3)	98 (64.9)
≥ 9 years	241 (39.9)	263 (43.5)	61 (40.4)	69 (45.7)	62 (41.1)	75 (49.7)	61 (40.4)	66 (43.7)	57 (37.7)	53 (35.1)
Health care, n (%)										
Yes	476 (78.8)	453 (75)	122 (80.8)	118 (78.1)	116 (76.8)	121 (80.1)	112 (74.2)	116 (76.8)	126 (83.4)	98 (64.9)*
No	128 (21.2)	151 (25)	29 (19.2)	33 (21.9)	35 (23.2)	30 (19.9)	39 (25.8)	35 (23.2)	25 (16.6)	53 (35.1)
Previous clinical trial participation (case group only), n (%)										
One	395 (65.4)		89 (58.9)		89 (58.9)		119 (78.8)		98 (64.9)	
Two to three	196 (32.5)		60 (39.7)		56 (37.1)		28 (18.5)		52 (34.4)	
Three to six	10 (1.7)		2 (1.3)		5 (3.3)		2 (1.3)		1 (0.7)	
More than six	3 (0.5)		0 (0)		1 (0.7)		2 (1.3)		0 (0)	

Notes: * $P \leq 0.001$; ** $P \leq 0.05$.

Abbreviations: COPD, chronic obstructive pulmonary disease; DM2, diabetes mellitus type 2; HT, hypertension; RA, rheumatoid arthritis.

Table 2 Comparison of the two most and least common answers between cases and controls

Questions and answers	Case group (n=604)	Control group (n=604)	P-value
1. Why do pharmaceutical companies do research?			
To cure more diseases and do so more effectively ^a	395 (65.4)	306 (50.7)	≤0.001
To find out whether new medications will be more effective and secure ^a	131 (21.7)	145 (24)	
Because research of new drugs is a business ^b	3 (0.5)	26 (4.3)	
So physicians can have new medications ^b	14 (2.3)	12 (2)	
2. Do you believe it is correct to perform research studies on humans?			
Yes	597 (98.8)	491 (81.3)	≤0.001
No	7 (1.2)	113 (18.7)	
3. Why do you believe that performing research on humans is reasonable?	n=597	n=491	
It is a good and reasonable option for people who cannot afford treatment by themselves ^a	247 (41.4)	162 (33)	≤0.001
It is reasonable as long as patients are closely monitored to identify the risks that could arise ^a	167 (28)	153 (31.2)	
It is reasonable only in the case of certain diseases such as cancer ^b	2 (0.3)	5 (1)	
4. Why do you believe that performing research on humans is “not” reasonable?	n=7	n=113	
Because human beings must not be treated like “guinea pigs” ^a	5 (71.4)	55 (48.7)	0.727
Because research is only conducted on people without other health care alternatives ^a	0 (0)	13 (11.5)	
Because in our country, medical researchers and the sites, where research is conducted, are not under surveillance ^b	0 (0)	13 (11.5)	
Because health is put at risk ^b	0 (0)	6 (5.3)	
5. What benefits do you believe Mexico, as a country, may obtain by participating in research studies conducted by pharmaceutical companies?			
To promote the development of clinical research centers and research physicians ^a	360 (59.6)	370 (61.3)	0.011
To offer expensive high-quality medical health care but free of charge to participants ^a	90 (14.9)	73 (12.1)	
To offer the participants medications not yet available to the general public ^b	73 (12.1)	73 (12.1)	
I do not believe there are any benefits ^b	5 (0.8)	20 (3.3)	
6. What benefits do you believe a patient may obtain by participating in a research study conducted by a pharmaceutical company?			
Participants receive free medical extra services besides the experimental drug such as education about their disease, nutritional evaluation and guidelines, medical equipment (eg, glucometer), etc ^a	391 (64.7)	343 (56.8)	≤0.001
Participants receive excellent medical care ^a	129 (21.4)	68 (11.3)	
In most cases, the benefits are minimal; instead, participants expose themselves to risks ^b	7 (1.2)	34 (5.6)	
I do not believe there are any benefits ^b	0 (0)	30 (5)	
7. In case of a serious adverse event related to the experimental drug that could lead to a complication or disability, do you believe that a study participant is protected?			
Yes	564 (93.4)	416 (68.9)	≤0.001
No	40 (6.6)	188 (31.1)	
8. Why do you consider the participant is protected?	n=564	n=416	
Research physicians take care of defending and protecting the participant ^a	414 (73.4)	282 (67.8)	0.037
I am aware that the company takes responsibility for and takes care of everything ^a	101 (17.9)	76 (18.3)	
The Ethics Committee will defend the participant’s position; the pharmaceutical company will have to comply with what they determine ^b	45 (8)	49 (11.8)	
9. Why do you consider the participant is “not” protected?	n=40	n=188	
Because in case a problem arises, no one will defend the patient properly ^a	16 (40)	74 (39.4)	0.167
Because the company can argue that the problem was not caused by the experimental drug ^a	15 (37.5)	87 (46.3%)	
Because medical researchers side with the company’s interests and not the patient’s ^b	3 (7.5)	17 (9)	
10. Do you believe that in research projects the participant’s health is put at risk?			
Yes	201 (33.3)	344 (57)	≤0.001
No	403 (66.7)	260 (43)	
11. Which do you believe is the reason people do risk participating?	n=201	n=344	
Because the health risks are minimal and if there was any problem, the physician would detect it on time ^a	69 (34.3)	83 (24.1)	≤0.001
Even though there are risks, the new medications offer more benefits than those offered to the general public ^a	58 (28.9)	73 (21.2)	
Because even though health risks are high, sometimes there is no other option to get clinical care ^b	9 (4.5)	56 (16.3)	
I am not aware that our health is put through any important risks ^b	8 (4)	5 (1.5)	
12. Why do you believe there are no health risks in these studies?	n=403	n=260	
I believe it is important that participants are under major monitoring by the physician ^a	213 (52.9)	131 (50.4)	≤0.001
I know there is a committee that makes sure that participants get more benefits than risks for their health. I trust them ^a	54 (13.4)	29 (11.2)	

(Continued)

Table 2 (Continued)

Questions and answers	Case group (n=604)	Control group (n=604)	P-value
Because I am sure that the physician would not invite me to participate if there were any risks ^b	18 (4.5)	44 (16.9)	
I simply do not believe there are risks involved ^b	12 (3)	6 (2.3)	
13. Do you believe that the most important reason that motivates a person to participate in this type of studies is the fact that everything is free, including medications?			
Yes	314 (52)	329 (54.5)	≤0.001
No	248 (41.1)	177 (29.3)	
I do not know	42 (7)	98 (16.2)	
14. Would you recommend others to participate in a pharmaceutical clinical trial?			
Yes	599 (99.2)	468 (77.5)	≤0.001
No	5 (0.8)	136 (22.5)	
15. Would you recommend a person without financial limitations to get clinical care to participate in a pharmaceutical clinical trial?			
Yes	497 (82.3)	361 (59.8)	≤0.001
No	107 (17.7)	243 (40.2)	
16. Would you participate in a drug research study of the pharmaceutical industry? (Control group only)			
Yes	–	367 (60.8)	
No	–	237 (39.2)	
17. Would you participate in another drug research study of the pharmaceutical industry? (Case group only)			
Yes	549 (90.9)	–	
No	7 (1.2)	–	
I do not know	48 (7.9)	–	

Notes: Data were given as n (%). ^aMost common answer. ^bLeast common answer.

to controls (68.9%). Correspondingly, less cases (33.3%) than controls (57%) considered their health was at risk if participating in pharmaceutical clinical trials.

For both groups, the fact that everything is free in clinical trials ranked as the most important motivation to enroll (cases 52%; controls 54.5%). Yet, cases (82.3%) would recommend participating in trials disregarding financial capability to afford medical care more so than controls (59.8%). Finally, 90.9% of cases expressed that they would participate in a drug research study again, while only 60.8% of controls would consider participating in a clinical trial.

Discussion

Participants' perception about clinical trials can be quite different depending on the severity, prognosis, and available treatment options of their disease. Most studies evaluating perceptions in clinical trials have been carried out in participants with cancer, HIV, and hepatitis C.^{17–24} These patients, frequently nonresponders to standard-of-care medications, are more likely to consider research treatments as an unavoidable alternative, making their perceptions biased and therefore unfit to be generalized to many other diseases. In addition, studies that have included a broad variety of disorders have not analyzed if the participants' diseases have affected their results.^{10,11,13,16} We studied an adult population with one of four common chronic diseases. These diseases all have many available and approved therapeutic choices and a low

life-threatening risk in the short-to-medium term. Also, most participants had access to private or social health insurance. Because of this, our findings represent a more accurate evaluation of the reasons and perceptions to participate in clinical trials funded by the pharmaceutical industry.

This multicenter study is the first to be conducted in Mexico exploring the perceptions of volunteer participants of industry-funded clinical trials. Its design allowed us to find that the degree of knowledge that participants have about the process of pharmaceutical clinical research directly influences their final perception, in contrast with the perceptions of nonparticipants with the same disease. Significantly, almost all cases (98.8%) considered that conducting research studies in humans is “correct” in contrast to just four out of five controls. Nearly one-tenth of controls mentioned the concept of “guinea pigs” when referring to research participants. The majority of cases and controls agreed that the ultimate purposes of clinical research are positive with the main concept being “to cure more diseases and to do so more effectively” and “to find out whether new medications will be more effective and secure”. Nevertheless, nearly nine times more controls than cases still believed that the main purpose of clinical research is business or that it is carried out just to “face competition with other companies”.

To better understand the meaning of these results, we need to consider that the general public image of the pharmaceutical industry is weak or highly negative almost everywhere.^{25,26}

There is public concern about the apparent judgment of medications as “nothing more than a consumerist tool”, and this idea is naturally extended to the clinical research funded by the pharmaceutical industry.^{27,28} Patients’ perception improves if individuals have participated in a clinical trial, as also observed by the Center for Information and Study on Clinical Research Participation.¹⁶ Significantly, in our report, nearly 95% of the cases clearly identified the benefits of their participation in the trial. In contrast, ten times more controls than cases believed that clinical trials granted none or minimal benefits to participants. Supporting these results, we found that 90.9% of cases would participate in another study, given the opportunity. Kost et al also found that 97% of the population surveyed would recommend research participation to family or friends.¹³ In our study, almost all cases (99.2%) would invite another person to participate in a clinical trial, in contrast to 77.5% of the controls. Furthermore, >80% of the cases would recommend participating in a clinical trial to anyone, irrespective of whether they could afford to pay for the treatment themselves, compared to only 59.8% in the control group, which is a significant difference. These findings reveal that participants perceive that pharmaceutical research offers a high-value medical treatment, regardless of the economic status of the individual.

Meropol et al reported that although oncology patients and physicians are aware of the trials’ benefits, three psychosocial barriers impact participation such as: random assignment, fear of receiving placebo, and fear of side effects.²⁹ In our study, significantly more cases (93.4%) than controls (68.9%) felt protected in case of an adverse event, mainly because they trusted the investigator and because they were “aware that the company takes responsibility and takes care of everything”. Almost one-third of the controls, however, had the perception that study participants are not protected and half of them believed that “in case a problem arises, no one will defend the patient properly”. In addition, significantly more controls (57%) than cases (33.3%) considered that in research projects the participant’s health is endangered; however, cases believed that the patients’ main reason to participate anyway is “because the health risks are minimal and if there was any problem, the physician would detect it on time”.

Participants who considered that their health was not at risk when entering a clinical trial (cases 66.7% vs controls 43%) did so because they believed that the patients are under close and permanent physician surveillance (cases 52.9% vs controls 50.4%) and because “I know there is a committee that makes sure that participants get more benefits than risks for their health. I trust them”. Campbell et al³⁰

reported how the negative reputation of research in human participants may impact study enrollment. This negative factor conveys the lack of understanding from the public about the methods and purposes of clinical research and the regulatory and ethical safeguards that the research process has nowadays to protect participants. The work invested on protecting the participants, frequently performed by professional researchers, by certified ethical committees, and by academic institutions, is generally unknown to the public; these evidences, in contrast to pharmaceutical industry-related negative events, are scarcely publicized.³ Therefore, it is necessary to provide potential research participants with adequate information.³¹ Furthermore, regulatory agencies in all countries must approve and certify that clinical research is carried out in professional research sites with committed and certified ethical committees, in order to guarantee that all issues that may arise during the execution of a clinical trial are properly handled. It is worthy to mention that the results of this study are in accordance with other reports from academic institutions also staffed with professional researchers.^{10–13} It would prove useful to test our survey on research sites with inadequately trained personnel participating as collaborators of clinical trials, participants with other diseases, and multinational collaborative studies.

Similarly to our findings, Llewellyn-Thomas et al showed that patients who choose to enter a clinical trial differ substantially from those who choose not to.³² As described earlier, almost in every item, we found significant differences between the perception of cases and controls. However, both groups of our study coincide in the notion that the most important motivation to participate in a study is because everything is free of charge. In Mexico, as a developing country, the cost of medical care should be considered as an important factor in the final decision to participate in a pharmaceutical trial. Despite the fact that >75% of the participants had access to social or private health insurance, they decided to participate in a clinical trial. As reasonably expected, our findings differ from those found in developed countries where “to help others” (64%) and “concern about the topic” (56%) were considered “very important” reasons to participate in a research study, and answers such as “to earn money” and “to obtain free health care” were less frequent.¹³ As recently reported by Ipsos Global Reputation Centre, negative perception about the pharmaceutical industry is worse in industrialized countries than it is in emerging markets, and interestingly Mexico is one of the countries where the industry is viewed less unfavorably.³³ We further support this concept because 96%–99% of the participants

in our study recognized the benefits that Mexico has by participating in pharmaceutical industry research. This information could help us have a better perspective of our results, when compared to experiences documented elsewhere. As Nathan recommended, our study shows how important it is to promote the recognized benefits of industry-funded biomedical research among the general public, considering that the lack of knowledge is producing a potential loss of confidence in this activity and is currently threatening the final purpose of clinical research.³⁴

Conclusion

Our multicenter study, in a developing country, in a large population of participants and nonparticipants of pharmaceutical clinical trials, most with access to health insurance and with one of four chronic and highly prevalent disorders with many available and approved treatments, could indicate that clinical trial participation has a positive influence on the perception of pharmaceutical industry-funded clinical research. Participants become aware of the benefits they obtain by enrolling in clinical trials and the rewards of conducting them for the whole country. They also may acquire a sense of security by perceiving that the site staff is capable of handling adverse events, view their current and future participation in clinical trials as a benefit to their health rather than a risk, and would recommend enrollment to others, regardless of their financial status. However, “free of charge medical attention” and “an option for people without health insurance” are strongly prevalent reasons for participation. All this information needs to be conveyed to clinicians, public health authorities, and the general population to overcome misconceptions. Still more information is needed regarding the evaluation of participants' perception in other issues that must be included in high-quality clinical research besides the measurement of the good clinical practice standards during clinical trial execution. Issues such as participant satisfaction, beneficence, value of participation, empathy, and participant information regarding their participation in the trial still need to be thoroughly analyzed.

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Disclosure

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