



National Institute on Minority Health
and Health Disparities

Univision Noticias Washington DC Special Report: Clinical Trials

This is part one of a two-part report. Original air date: May 16, 2016

<http://noticias.entrvision.com/washington-dc/2016/05/16/estarias-dispuesto-a-negociar-con-tu-vida-voluntarios-se-someten-a-experimentos/>

Will you be willing to risk your life and volunteer for clinical trial research studies to advance scientific knowledge? Volunteers submit themselves to experiments

Before a medication goes on sale in the market, it must pass a trial phase and there are those who are willing to participate in clinical trials.

Transcript, part 1

In the United States, clinical trials have been carried out for decades. However, most participants of the trials to test medications and treatments in human beings have been White and, therefore, the reaction many medications would have on Latinos/Hispanics or other race/ethnic groups remains unknown.

The National Institutes of Health (NIH) are studying some treatments with new medications, but here is something interesting:

Dr. Eliseo J. Pérez-Stable, Director of the National Institute on Minority Health and Health Disparities (NIMHD): "Many medications are approved having almost no Latino participants on the clinical trials carried out to approve such medication. The FDA approves new medications, but pharmaceutical companies carry out [a majority] of clinical trials. Although 16% of the population of the country is Latino, only 1% of the participants in clinical trials are Latinos."

[Cariny Nunez, MPH, Public Health Advisor, Food and Drug Administration]: "It is important for Latinos to participate in clinical trials because it helps researchers find out which differences affect these groups and how to treat and fight diseases such as cancer, diabetes and HIV/AIDS."

Leticia, former clinical trial participant: "I had lots of questions because I didn't know what it was about."

Leticia took part in a study on cancer and, despite her fears, when she participated she had access to all the information.



Unidentified Speaker: "We make sure the volunteers are protected and to inform them in detail what it is about, what are the risks, what are the benefits, and also provide them with any new information obtained from pharmaceutical companies."

That was key to Leticia.

Leticia: "And yes, I would take part in other studies again; I would love to because I know it will be beneficial."

Many people participate in studies because of the money, but the truth is that payments are not as high as one might think.

Dr. Pérez-Stable: "This compensation is usually justified as *for your time*, it doesn't measure the risk or the kind of work, because if we give too much money, it seems we are buying someone's participation in a coercive way and that is not ethical either."

If participants do not receive so much money to take part in clinical studies, then, who is really risking their life? We will tell you tomorrow on the second part of this special report.

This was Edwin Pitti, Univision.

This is part two of a two-part report. Original air date: May 16, 2016

<http://noticias.entravisión.com/washington-dc/2016/05/16/medicamentos-pueden-tener-diferentes-efectos-segun-su-ascendencia/>

Medications may have different side effects, according to your ethnic background.

Hispanics could be affected if they consume medications that have only been evaluated on another race/ethnic group.

Transcript part 2 (starts around minute 05.41)

The National Institutes of Health do not hide the fact that there have been fatalities in some studies, but they specify that in those cases, the patient was already ill, almost at an end stage. However, they highlight the positive aspects.

Dr. Pérez-Stable: "In the last 40 years, mortality rates due to cardiovascular disease have dropped by 70% in the US. This means there was a dramatic reduction on the leading cause of death."

Reynaldo, a retired professor, took part and something surprised him.

Reynaldo, former clinical trial participant: "I realized what it means to work or take part in a clinical experiment. It was very good because they were monitoring my health at the same time."

Dr. Pérez-Stable: "The medical care one receives when participating in a clinical trial is considered better than the average medical care."

The FDA requires pharmaceutical companies to present the results of their clinical studies in order to approve a medication. However, diversity is not compulsory, and that is where we need more knowledge, regarding how Latinos/Hispanics would react to some medications.

FDA representative #1: "In recent years, a law asking the FDA to carry out research on how medical products affect different subgroups was approved."

The situation is more complex than it looks. The health system crisis across the globe has a common denominator, which is access to medicines. This is how scientist Ibis Sánchez Serrano explains it on his book *The World's Health Care Crisis*.

Ibis Sánchez Serrano, scientist: "As science advances, as medicine progresses, we face a dichotomy: human beings are increasingly becoming sick beings."

In the United States, almost 13% of the annual health budget is destined to developing medications, an area controlled by pharmaceutical companies.

Ibis Sánchez Serrano: "The cost of medications is increasing, and in the United States it is increasing at a pace more than twice the rate of inflation, which is causing great concern."

The NIH says this happens because we live in an open market system, but they insist the benefits are greater.

Dr. Pérez-Stable: "Although we have learned a lot about how to control and prevent diabetes, the number of cases of diabetes is increasing, which means the problem would be even worse without this knowledge."

Despite the dealings of pharmaceutical companies and their political influences, experts assure that today, clinical trials are safer than they were 20 or 30 years ago. Therefore, the FDA recommends that, if you want to take part in a clinical trial, you should be informed at all times, especially if there is any risk.

This was Edwin Pitti, Univision.