EVALUATION OF PUBLIC USE OF THE FDA's WEB-BASED CLINICAL RESOURCES

by

JUANA VIETA

(Under the Direction of Paul J. Brooks)

ABSTRACT

The FDA is committed to protect and promote the public health and sets special considerations into regulations, guidances and new strategies to allow therapies of life threatening diseases such as cancer to enter the market more rapidly. But these therapies will not reach the market unless mandatory regulations to demonstrate safety and efficacy in human subjects are met. The recruitment of volunteers required to participate in clinical trials is a challenge. Cancer clinical trials are essential to obtain more and better prevention methods and safer and more effective treatments against the cancer diseases.

The FDA provides web-based tools to browse information with regard to cancer clinical trials. The general public is not aware of these browsing tools. This research assessed the utilization of the FDA web site to procure current health information in particular about cancer clinical trials.

INDEX WORDS: FDA website, awareness of cancer clinical trials, cancer patients

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## DEDICATION

This thesis is dedicated to my siblings for their continuous encouragement. I also want to extend a special dedication to my husband Tito and sons Gilberto and Yulian for their support, help, and patience while I was working long hours to accomplish this study.

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# CHAPTER 1

## INTRODUCTION

There were 562,340 cancer deaths in 2009. In 2010, 1,529,560 new cancer cases were diagnosed in USA compared to 1,479,350 new cases in 2009[1]. Approximately 1,500 people die of cancer every day[2]. It is essential to conduct clinical trials to obtain more effective medical products to control and potentially cure cancer. The majority of cancer patients are unaware that clinical trials could be a treatment option for their condition. Accessible tools to web-search for clinical trial information are critical. The Food and Drug Administration (FDA, also called the Agency) keeps evolving and optimizing their web page with the goal of providing better web based browsing tools that assist the general public[3]. The FDA is working with new strategies to enhance the clinical trials system and promote innovation through science, ultimately accelerating safer and more effective medical products approval. All information about current, completed or terminated clinical trials can be found in the FDA's website Science & Research portal, because all clinical trials must be registered in the ClinicalTrials.gov databank. Therefore, the FDA's website is an appropriate web source to find cancer clinical trials information. Unfortunately, the general public is unaware of these browsing tools.

It is the belief of the researcher that people do not browse the FDA website and are not aware of the browsing tools the FDA provides. The purpose of this research study was to investigate if members of the general public, who have an interest in finding information about treatment options for cancer, visit the FDA's website for information related to clinical trials of cancer diseases. This assessment of whether or not people search the FDA's website was conducted in

the form of an online questionnaire; therefore this study is intended for population with access to the internet. This survey also evaluates which websites cancer patients use to gain cancer related information.

Two ongoing clinical trials registered at Clinicaltrial.gov, CRLX101 and I SPY 2 Trial, were included in the survey to determine the awareness of cancer patients about current clinical trials. For this study it was expected that the majority of the patients who might benefit from CRLX101, I SPY Trial and other promising investigational therapies are unaware of clinical trials for which they might be eligible and benefit do not search the clinical trials portal provided in the FDA's website. This survey also sought to discover if cancer patients would participate in clinical trials if they were aware that these could be a treatment option.

# CHAPTER 2

# CLINICAL TRIALS

## 2.1 CANCER DISEASE

Cancer is a term for diseases in which abnormal cells divide and grow without control. There are many kinds of cancer, but they all start because abnormal cells grow out-of-control. Cancer cells can invade and grow into other tissues, something that normal cells cannot do[4].

The different types of cancers are carcinoma, which is a cancer that begins in the skin or in tissues that line or cover internal organs. Sarcoma is a cancer that begins in bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue. Leukemia is a cancer that starts in blood-forming tissue such as the bone marrow, and causes large numbers of abnormal blood cells to reproduce and enter the blood. Lymphoma and multiple myeloma are cancers that begin in the cells of the immune system. Central nervous system cancers or malignancy are cancers that begin in the tissues of the brain and spinal cord.[5]

External factors that cause cancer include genetic factors, the use of tobacco products, unhealthy diets, lack of physical activity, certain types of infections and environmental exposures to different types of chemicals and radiation[6].

A common treatment for cancer is chemotherapy. The therapy uses drugs to destroy cancer cells, to stop them from spreading and to slow the growing process. Many of these chemotherapies also destroy the good cells. The treatment is followed by a period of rest to allow the body to build new healthy cells. The time of the treatment varies and might be severe, debilitating and alter the quality of life for many of the patients[7].

## 2.2 THE CONCEPT OF CLINICAL TRIALS

Clinical trials are research studies of human subjects with the purpose of gathering medical information about new methods or treatments to determine how well the new medical approach works in people. These studies are essential to obtain enough evidence to confirm the safety and clinical benefit of the product. The trials provide data to demonstrate if health risks are outweighed by the benefits offered to patients. The objective of the clinical trial must be achieved by exposing as few people as possible to the experimental treatment to guard their safety. That is why clinical trials are evaluated in a systematic way that is called phases. Each phase meets a purpose before the product is considered safe enough to move forward to the next phase[8,9].

Phase I trials**:** The first study in a small number of healthy people (20-80) to determine a safe dose of a new drug, the dosage frequency and the method how it should be delivered. For instance, the drug can be taken intravenously or delivered orally.

Phase II trials**:** A phase II trial continues to test the safety of the drug and begins to evaluate how well the new drug works for a particular indication or disease using a larger population (100-300) to begin to introduce more statistical relevance into the overall study.

Phase III trials: In this phase the treatment is tested in comparison to the current standard of treatment for the target condition. Volunteers are randomly assigned to a standard group or new treatment group. Phase III trials often enroll large numbers of people (1000-3000) and may be conducted at many doctors' offices, clinics, and cancer centers nationwide.

Phase IV trials: This phase refers to the monitoring of the drug or treatment after it has been approved by the FDA. Investigators evaluate side effects, risks, and benefits over a longer period

of time and in a larger number of people. This phase often involves thousands of people using the treatment.

## 2.3 CANCER CLINICAL TRIALS

Cancer research plays a critical role in the overall contribution to the progress and advances of more medical discoveries against cancer diseases. The research allows the health care professional to understand more about the diseases and new technology. The progress made through clinical trials allows more cancer patients to be treated with new medicines and many to live longer because the subjects participating in cancer clinical trials could be seriously ill or dying[10]. These clinical trials also have the purpose to demonstrate safety and effectiveness of promising approaches to prevent the diseases, or diagnose or improve the quality of life, and treat cancer. Only 3% of cancer patients receive treatment for their cancer disease by participating in a clinical trial[11]. It is essential to increase the participation rate of cancer patients in clinical trials to achieve faster progress over cancer diseases affecting the American population.

Prevention trials: These assess new approaches, such as new interventions, medicines or nutritional supplements that doctors believe may lower the risk of acquiring certain types of cancers. These trials evaluate ways to prevent cancer in people who have not had cancer but do have a high risk of developing a specific type of cancer. People who have had cancer in the past might also participate to prevent the return of the original cancer or lower the risk of developing a new type cancer[12].

Diagnostic trials: These trials usually involve people who have some signs or symptoms of cancer. These trials study new tests or procedures that may help identify, or diagnose, cancer

more accurately such as the "Liquid Biopsy", a microfluidic chip being developed by Johnson & Johnson in collaboration with Massachusetts General Hospital. The purpose of the “Liquid Biopsy” is to identify cancer cells in blood[13].

Screening trials: These assess new ways of finding cancer early. These trials usually involve people who do not have any signs or symptoms of cancer, but they may have a high risk of developing a certain type of cancer because of family history of cancer or a history of being exposed to cancer-causing substances. In these trials screening tools might include imaging, laboratory tests and genetic tests. The goal is to detect and treat cancer earlier for a better chance of effective treatment[14].

Quality of life or supportive care trials: These trials are focused on the comfort and quality of life of cancer patients and cancer survivors. These evaluate new ways to ease the side effects caused by the disease or its treatments, and they determine how a specific type of cancer or the treatment affect a person’s everyday life[15].

Treatment trials: They evaluate the effectiveness of new treatments or new approaches of using current treatments, new drugs or new combinations of current treatments, new surgery or radiation therapy techniques, vaccines, and other newer methods such as gene therapy, in people who have cancer. In the past, clinical trials were seen as the last resort for patients who had no other treatment choices. There are many cancer clinical trials that could be valuable treatment option for patients[16].

## 2.4 CONFLICT OF INTEREST IN CANCER CLINICAL TRIALS

All clinical trials are regulated by ethical codes to protect the subjects lead by a controlled protocol and a study plan that details what the clinical investigator will do in the trial. The

Informed Consent (IC) and Institutional Review Boards (IRB) found in 21 CFR parts 50 and 56 were created to protect human subjects participating in clinical trials. The IC is a legal document stating the purpose of the research, the procedures, the benefits and risk of the trial that must be understood and signed by the subject and the researcher. The researchers are obligated to keep the participant updated with progress and changes in the study. The IRB is a board or committee that approves the initiation and conduct periodic reviews of the biomedical research.
During the clinical trial the medical team that may include doctors, nurses, social workers and other health care professionals are responsible to check the health of the participants at the beginning of the trial, carefully monitor during the trial, and stay in touch after the trial is completed.

### 2.4.1 THE CANCER EXPERIMENT AT THE FRED HUTCHINSON CANCER RESEARCH

The Fred Hutchinson Cancer Center (The Hutch in Seattle) is funded by the National Cancer Institute, and at the time it was the only federally tax-supported nonprofit cancer center in the northwest. Both a blood-cancer experiment from 1981 to 1993 and a breast-cancer experiment from 1991 to 1998 were conducted at this center. Numerous unethical issues in these cancer experiments were identified and were discussed in the Seattle Times *"Uninformed Consent"* articles published in March 11-15 of 2001[17]. The patients who volunteered in the blood-cancer experiment received antibodies donated by tissue-matched siblings to kill white-blood T-cells in the bone marrow after the transplant. Most of the patients had 50 percent or better chance of survival with just the transplant which was the standard therapy. Others had a 10 to 20 percent chance for cure without the antibodies. However, 80 of the 82 patients participating in the study

died. At least 20 of them died from the experiment and the rest sooner than they would have with no treatment at all.

In the breast-cancer experiment the patients were to receive pentoxifylline or PTX, the experimental treatment, to reduce the toxic side effects caused by the cocktail drugs for the chemotherapy. Since many patients vomited from chemotherapy, PTX was to be given intravenously (IV) in lieu of the oral route. However, when the investigators were notified of the unavailability of the IV drug, doctors were instructed to cross out any reference of the IV in the patient IC forms. Patients evaluate whether or not to participate in these trials based on what they were initially told. Therefore, the subjects were not aware of this change and died from the toxic side effects of chemotherapy drugs that IV PTX could have prevented. Patients were enrolled without being informed about prior deaths. Moreover, relatives and cancer participants were unaware that the Center and its doctors had a financial interest in the experiment[18]. Because John Pesando, MD, a former Hutch researcher became the whistle-blower, relatives of past cancer patients learned about the unethical situations, sued the center and a judge ruled the Hutch as negligent.

The Fred Hutchinson Cancer Research Center has improved their system by adopting tougher rules to comply with the federal requirement of financial disclosure by clinical investigators, 21 CFR 54, restricting researchers from having financial conflicts of interests in medical experiments. Researchers are not allowed to own stock or any other equity in a company for which they are doing research and must disclose all consulting fees and any financial ties to the companies involved with research projects[19].

### 2.4.2 THE UN-ETHICAL DEATH OF JESSE GELSINGER

Jesse Gelsinger was 18 years old when he enrolled in a gene therapy research project conducted by the University of Pennsylvania in 1999. The institute is one of the largest academic gene therapy centers in the world, and it retains links to many private biotechnology companies. Jesse suffered from a disease called partial ornithine transcarbamylase (OTC) that makes him unable to metabolize ammonia. He could have survived on a restricted diet and special medications; however, he participated in a gene-therapy trial in the hope of a cure. Within hours of the gene treatment his immune system raged out of control and four days later he died[20].

Several ethics rules were violated. During the investigation, the FDA found that patients in the study had not been properly informed of the risks involved in the trial. Some subjects were too sick to have been included in the experiment. Jesse's high ammonia levels should have excluded him from the trial. Furthermore, the FDA found that the Institute IC form had been altered to avoid reporting that monkeys died in similar tests as Jesse and to avoid reporting that two patients experienced serious side effects from the therapy. FDA found numerous other violations against the protection of the participants. As a result the FDA shut down all gene therapy trials at the Institute which interrupted in progress studies for cystic fibrosis, lung cancer, melanoma, breast cancer, muscular dystrophy, and brain cancer[21,22]. The principal investigator, Dr. James Wilson, and the University had financial interests in the study. This case shows how ethical violations motivated for personal financial gain, contributed to Jessie's death and the delayed of important scientific research.

### 2.4.3 THE MELANOMA VACCINE TRIAL

The Melanoma Vaccine clinical trial of Dr. Michael J. McGee was conducted at the University of Oklahoma in 1999 is another controversial clinical cancer study. Cherlynn Mathias, the research nurse and coordinator for the study was the whistle-blower. She reported that unethical issues occurred in this research. For instance, one female patient notified the study coordinator that she was pregnant, showing her concern from a warning in the IC of potential serious effects the drugs may cause on growing fetus that might include serious birth defects. Dr. McGee assured that the vaccine could not pass through the placenta and encouraged her to continue with the treatment[23]. He claimed that he gave the drug to his father-in-law because it was the best vaccine against the disease and told patients that other patients had responded to the treatment. More than a third of the subjects developed severe side effects. Some patients were allowed to self inject the vaccine, and they stored the vaccine at home in their refrigerators against good clinical practices of drug accountability and proper storage. Furthermore, subject safety was a concern; subjects without careful medical monitoring could have a serious reaction to the drug. Ms. Mathias reported issues with the protocol, the IC, and the manufacturing environment for the vaccine. This information became public knowledge because she contacted the Office of Human Research Protection[24]. This study was part of a $700,000 project funding, in which Dr. McGee had financial interest. In 2009, the Food and Drug Administration banned Dr. J. Michael McGee from further clinical investigations for failing to comply with federal regulations[25].

These examples help demonstrate that financial conflicts of interest can extend not only to the institutions, but also to the researchers themselves. The cancer research at the Hutch center, the gene-therapy trial, and the Melanoma Vaccine trial took place after the very well known

Tuskegee Syphilis Experiment from 1928 to 1972 that raised so much concern about the protection of the rights of research subjects.

The former lack of safety and protection for the participants in clinical trials may cause fear in potential subjects about clinical trials by perceiving that some scientists administer unsafe drugs to human subjects under unsafe conditions for their personal financial benefit.

## 2.5 OVERVIEW OF TWO CURRENT CANCER CLINICALTRIALS

Approved treatments and ongoing clinical trials are adapted to the type of cancer. Study CRLX101 (Formerly Named IT-101, NCT00333502) is for the Treatment of Advanced Solid Tumors, and I-SPY 2 TRIAL (NCT01042379) Neoadjuvant and Personalized Adaptive Novel Agents for the treatment of Breast Cancer are just two ongoing cancer clinical trials listed in ClinicalTrials.gov database.

### 2.5.1 CRLX101 (IT-101)

CRLX101 is a Camptothecin (CPT) treatment. CPT is a compound that has shown remarkable anticancer activity. It was unexpectedly discovered as a result of a research effort to find a cheap plant-derived source for cortisone using the bark and stem of the native Chinese tree Camptotheca acuminate. The tree had a long history of use in traditional Chinese medicine as described in the book "Drug Discovery and Traditional Chinese Medicine, Science, Regulation and Globalization" edited by Yuan Li. It was discovered in 1966 by Monroe E. Wall at Research Triangle Institute with the support of the National Cancer Institute[26,27]. CPT has low solubility and high cytotoxic effects demonstrated in an in-vitro study in human epitheliod sarcoma, colon, breast and ovarian carcinomas, glioblastoma, and neuroblastoma cell lines[28].

CPT selectively inhibits the Topoisomerase 1 (Top1)- DNA intermediate. Top1 is an enzyme that winds and unwinds DNA in order for DNA to control the synthesis of proteins and to facilitate DNA replication. Good cells are also affected by CPT by trapping the catalytic Top1-DNA[29,30,31]. Therefore, the damaged DNA cannot produce more damaged DNA or cancer cells. But also the good DNA cannot produce more of the good DNA, and these cells die too.

CPT is under research using a new technology to deliver the drug directly into the cancer tumor (targeted therapy). The technology is called CRLX101, formerly named IT-101 Nanoparticle Drug for Cancer Treatment[32]. It was developed by Dr. Mark Davis and associates at Insert Therapeutics, Inc., hence the name of IT-101, now Cerulean Pharma Inc. (Cambridge, MA)[33,34]. CRLX101 is a linear, cyclodextrin-containing polymer conjugate of CPT[35]. The product is formulated for the polymer conjugate to self-assemble into nanoparticles. Nanoparticles are powder, clusters, or crystals between 1 to 100 nm[36]. CRLX101 is a much larger particle compared to many current chemotherapy drugs. In fact, CRLX101 is too big to diffuse through normal blood vessels throughout the body. Cancer tumors do not have normal blood vessels; rather, the blood vessels have holes with chaotic arrangement allowing the entrance of CRLX101 directly into the tumor, sparing non-diseased tissues [37]. CRLX101 is specifically formulated to have the treatment enter through the loops or holes formed by the abnormal blood vessels that feed the cancer tumor through the cancer tumor itself. CRLX101 technical principle is to increase the exposure of tumor cells to the chemotherapeutic drug while minimizing the toxic side effects[38,39].

A phase I clinical trial of CRLX101 tested dosage and safety against advanced solid tumors in patients with all cancers, including ovarian cancer, lung cancer, and pancreatic cancer. A phase II study to compare the proportion of patients without evidence of disease progression to patients

with ovarian cancer between CRLX101 and placebo treatments was scheduled[40]. This study would have assessed the effect of CRLX101 on delaying ovarian cancer progression however; the study was terminated due to poor trial recruitment.

Another trial has been initiated to investigate CRLX101 in the treatment of advanced solid tumors with patients who must have already failed other conventional approaches to minimize any additional health risk due to the unknown activity of the new therapy [41].

The first volunteer cancer patient to get the CRLX101 treatment was diagnosed with pancreatic cancer[42]. Two-thirds of his pancreas was removed followed by conventional chemotherapy. A year later the cancer returned, spreading quickly into his lungs. After six months of experimental CRLX101 treatment, his tumors showed holes inside as an indication that they were dying. A year following CRLX101 treatment, he was stable. During his initial chemotherapy treatment with the conventional anti-cancer drugs, he experienced the severe side effects common to the chemotherapy such as **a**nemia, nausea and vomiting. This time under the CRLX101 treatment, he only reported that the taste of some foods was different. Initially, he was expected to live only a few months, but CRLX101 treatment offered better prognosis.

Based on this clinical case, CRLX101 might be a promising cancer therapy able to protect non-cancerous cells in the body and may prevent the patient from experiencing severe health stresses caused by conventional chemotherapy. CRLX101 technology might allow another way to treat cancer tumors by delivering a highly effective drug with low toxic exposure to the patient supported by pre-clinical data that suggests CRLX101 is reasonably effective on a variety of cancer tumors[43,44].

### 2.5.2 I SPY TRIAL 2

The I SPY Trial 2, (**I**nvestigation of **S**erial Studies to **P**redict **Y**our **T**herapeutic **R**esponse with **I**maging **A**nd mo**L**ecular **A**nalysis **2**) is a second investigational study, which success relies on the completion of clinical trials[45]. The I SPY TRIAL 2 is a trial for women with newly diagnosed advanced breast cancer[46]. The study will assess whether the efficacy of phase II investigational drugs from different drug companies in combination with standard chemotherapy is better than the efficacy of standard chemotherapy alone. The objective of the study is to identify improved treatment regimens for subsets on the basis of biomarker signatures of their disease to establish predictive and prognostic tools for breast cancer patients achieving personalized breast cancer therapy.[47]

The standard care for this type of cancer includes neoadjuvant therapy that refers to the administration of therapeutic agents prior to the main treatment, which is surgery. In the first phase of I-SPY Trial five investigational drugs, representing different chemical mechanisms for attacking the cancer, developed by Abbott Laboratories, Amgen and Pfizer Inc. will be tested[48]. The trial will allow the screening of up to 12 investigational cancer drugs to reduce tumor size before the surgery. The end point for response to treatment will be the measurement of pathologic complete response (pCR) meaning no residual cancer in the breast or lymph nodes. The trial is designed to learn about each drug's biomarker signature by graduating, dropping, and adding new drugs as the study progresses. The biomarkers are indicators that help measure the progress of a disease or the effect of a treatment. A biomarker could be any molecule whose presence, absence, or abnormal concentration suggests an abnormal physiological status associated with an injury or disease. Drug-related biomarkers indicate whether a drug will be effective in a specific patient and how the patient’s body will process it.

Treatments with no benefit will be dropped from the study. The treatments that are more effective than the standard therapy will be selected for use in a specific type of patient as these treatments accrue during the trial. Subjects will be assigned into treatments guided by the results of previous subjects with similar tumor characteristics to increase the chance of getting more subjects into the treatments that will be identified as more effective than the standard therapy.

In 2010, an estimated 207,090 new cases of invasive breast cancer are expected to be diagnosed in women in the U.S., along with 54,010 new cases of non-invasive (in situ) breast cancer. About 39,840 women in the U.S. are expected to die in 2010 from breast cancer[49]. I SPY 2 Trial is a multicenter study, expecting enrollment of 800 women with breast cancer. Less than 0.4% of the estimated new cases of invasive breast cancer patients are needed to participate in I SPY Trial, and it is very important to gain their participation to obtain statistical relevance to the study.

The goal of I SPY Trial is to use the patient's medical and biological information to specifically tailor medical treatments for breast cancer patients. Identifying personalized therapy is more effective than collective therapy. In this adaptive design, several investigational drugs will be screened in the same study. Ineffective treatments will be identified faster than in traditional trials, more subjects will be assigned into more effective treatments, and biomarkers signatures will be validated for all screened drugs to establish predictive sophisticated bioinformatics tools.

# CHAPTER 3

# CHALLENGES TO RECRUIT CANCER PATIENTS FOR CLINICAL TRIALS

## 3.1 INTERRUPTED CANCER CLINICAL TRIALS

The FDA ClinicalTrials.gov is a databank to register and maintain information regarding the results and progress of clinical trials. Previously, it was called the Protocol Registration System (PRS) established by the National Institutes of Health (NIH)/National Library of Medicine (NLM). The study record in Clinicaltrial.gov indicates the reasons for terminating registered studies can be found in the databank. Business decisions, any deviations to the protocol, lack of medical or scientific merit, not having re-supply medication, lack of funding, low efficacy or high adverse reactions related to the treatment, and poor enrollment of subjects are the most common reasons to terminate clinical trials.

The article "One in Five Cancer Clinical Trials Is Published: A Terrible Symptom-What's the Diagnosis?" in *The Oncologist*, the Journal of the Society for Translational Oncology, in September of 2008, presented the critical issue of poor enrollment of cancer patients in clinical trials. It reports that almost 50% of the cancer clinical trials failed to accrue and reach endpoints, 60% of trials opened for 5 years had fewer than 5 patients per site, and, for more than 20% of studies, not a single subject accrued. For all National Cancer Institute trials between 2000 and 2007, around 50% of the studies achieved minimal stated accrual goals[50]. Most likely these incomplete studies will not provide the expected medical knowledge and conclusions cannot be drawn out of the data.

## 3.2 REASONS THAT PREVENT CANCER PATIENTS TO ENROLL IN CLINICAL TRIALS

*The Basic Workbook*, published by the National Cancer Institute in August of 2002, identified some reasons that challenge the participation of cancer patients in clinical trials. These reasons are related to both the physicians and the patients[51].

Many physicians fail to inform their patients about clinical trials include. Physicians are not always aware of available clinical trials or believe that standard therapy is always best; some assume that trials are inappropriate for their patients. Physicians tend to fear they may lose control of their patient's care; do not adequately understand how clinical trials are conducted and because of concerns about how their patients will react to the suggestion of participating in a clinical trial. Finally, participation in a clinical trial program may incur additional costs and expenses for the doctors, and this would add costly administrative burden, especially if they might not be reimbursed. Physicians play a very important role in making patients aware of clinical trials. The physician is the most qualified professional to inform the patients about the benefits and risks of the clinical trial, and they should be the facilitators in the enrollment process.

In addition to physician concerns, many cancer patients also avoid clinical trials because they often believe that standard care is better than the experimental option, because travel becomes a burden for many cancer patients and the belief that nearby appropriate trials do not exist prevents them from participating. Cost is a limiting factor because health insurance does not cover all clinical trials. Awareness of historical abuse to research subjects does not encourage cancer patient's trust in trials. The fear to become instruments for experimentation creates apprehension and skepticism about the quality of care that would be provided to the subject in the clinical trial. Patients may face personal obstacles such as being away from work and family or not meeting

the eligibility criteria. The main reason preventing cancer patients from participation in clinical trials is the lack of awareness that clinical trials could be a cancer treatment option[52].

The National Cancer Institute (NCI) makes reference to The 2000 Cancer Clinical Trials Study (CCTS) a Harris Interactive survey. This is an examination of the attitudes of a national sample of American adults toward participation in cancer clinical studies that was published in the *Journal of Clinical Oncology* [53]. These results indicate that the primary problem is not the attitudes of patients. Low participation of cancer patients in trials may occurs because the clinical trial may not be appropriate for the volunteer, a large number of patients fail to meet the inclusion criteria, and the majority is not even aware of the opportunity. Those that may qualify for the studies do not always receive the information from their physicians. The CCTS survey, noted that 85% of cancer patients are unaware that a clinical trial might have been a possible treatment[54,55].

In 2005, The Coalition of Cancer Cooperative Groups and Northwestern University conducted another survey with approximately 2000 cancer survivors of newly diagnosed cancer. This survey shows that only 9% were informed about the possibility of participating in a cancer clinical trial. Those who participated in clinical trials claim satisfaction with the experience[56,57]. Five years after the Harris Interactive CCTS survey, this second survey shows that more than 90% of potential cancer participants in clinical trials were unaware that trials were a treatment option. In other words, there has not been change on awareness of clinical trials as treatment option among cancer patients.

# CHAPTER 4

# OVERVIEW OF FDA'S STRATEGY TO SPEED THE APPROVAL OF NEW MEDICAL PRODUCTS

The Food and Drug Administration (FDA) is the agency under the United State Department of Health & Human Services responsible for the approval and safety of consumer products. As the new century approached, industry underwent a radical change in technology[58]. The manufacturing of medical products has changed from labor intensive processes to high-tech production. The use of biomarkers in early drug development is rapidly increasing in the industry. These are being studied to evaluate and treat critical diseases such as cancer, autism; to determine coronary artery surgery; to detect and identify cardio-toxicity during chemotherapy; for the diagnosis of cervical biopsies; for determining exposure to environmental contaminants; and for many other applications under evaluation[59,60,61,62]. The study of the human genome is a growing scientific field allowing personalized or tailored treatments[63]. Researchers are working with stem cell-based therapies for repairing, replacing, restoring, or regenerating damaged cells, tissues and organs[64].

Since the FDA regulations, guidance, and experience have been designed for more conventional technology, it has been challenging for FDA to keep up with the complexity of new technology.

## 4.1 CRITICAL PATH INITIATIVE

The FDA is designing strategies to speed to the market safe and effective innovative medical products as fast as new technology is emerging, without compromising the safety and protection of subjects in clinical trials. The Critical Path Initiative (CPI) was created in March of 2004[65]. CPI is a nationwide collaboration with other Federal, academic, scientific, and private industry organizations assisting with the development of new tools to facilitate innovation.

The CPI is the FDA's national strategy to change the current way of approving medical products by using more scientific elements in the development, evaluation, and manufacturing process. The CPI project supports the use of pharmacogenomics during the product development to facilitate personalized medicine. Genomics studies the DNA sequencing of the human genome used for monitoring diseases, diagnosing patients, and even building things. The FDA has created a program that includes guidance and educational material in genomics to ensure its proper utilization to protect public health[66,67]. The majority of current product development programs are discontinued after extensive cost and time have been invested. The CPI goal is to decrease the duration of the development and approval process by designing more scientific strategies for new technology in the fields of genomics, imaging, and informatics applied during the product development to improve the accuracy of tests that predict the safety and efficacy of potential medical products.

The FDA critical path list is a landmark report that presents the 76 areas of possible improvement classified in six categories[68]. The modernization of running clinical trial sciences to make trials safe and efficient is an area of important interest listed in the CPI. Modern clinical trial tools may be used for eliminating potentially unsafe products and identifying potentially

good candidates earlier in the development process. Also the development of target cancer therapies to allow more effective treatment for the patients is a field of interest indicated in the critical path list.

### 4.1.1 HSP/BIMO INITIATIVE

The Human Subject Protection (HSP) and the Bioresearch Monitoring (BIMO) Initiative was launched in 2006, as a part of the CPI[69]. HSP/BIMO was created for modernizing and strengthening the protection of subjects and the data integrity in all clinical trials. The goals of BIMO program are to protect the rights, safety, and welfare of subjects involved in clinical trials; to determine the accuracy and reliability of clinical trial data and to assess compliance with FDA's regulations.

Among the BIMO achievements is the mandatory registration of Institutional Review Boards (IRBs), captured in 21 CFR 56.106 effective on January 2009[70]. It facilitates the identification and tracking of the IRB's. Also, effective on March 2011, "elements of informed consent", 21 CFR 50.25 will be amended to require a specific statement in the informed consent documents and processes that clinical trial information for the investigational therapy will be entered into the ClinicalTrials.gov databank[71]. It enforces the registration of clinical trials. They currently proposed to amend the regulations that the disqualification of a clinical investigator received for a particular investigational product be extended for all FDA-regulated investigational products[72]. FDA/BIMO will require sponsors to report information of any person engaged in falsification of data in any way to help ensure the validity of the data supporting the product applications.

### 4.1.2 CLINICAL TRIALS TRANSFORMATION INITIATIVE

Clinical Trials Transformation Initiative (CTTI) was created in November 2007 under the CPI for streamlining clinical trials. It is a public-private partnership (PPP) agreement between the FDA and Duke University. This collaborative work involves several government agencies, private industries, clinical research organizations, professional societies, investigator groups and academic institutions. CTTI's main goal is to modernize the system to increase the quality and efficiency of clinical trials.

CTTI is assessing ideas to establish national standards for conducting clinical trials, to enhance the IRB system avoiding duplication of efforts, to establish accreditation for clinical investigators and research sites, and to standardize the use of electronic data management. The Clinical Investigator Training Course and the Site Metrics for Study Start-Up projects were created to meet these needs.

The Clinical Investigator Training Course is an annual 3 day training course co-sponsored by FDA and CTTI. It was initiated in November 2009 for clinical investigators on scientific, ethical, and regulatory aspects of clinical trials. The goal of the program is to keep clinical investigators up to date with regard to the FDA's perspectives on new safety concerns, adverse event monitoring, compliance with legal and ethical obligations of clinical research, and acceptable scientific and analytic standards in clinical study design. It was created to address the lack of committed, well-trained and experienced clinical investigators. The expectation is to ensure that clinical investigators are aware of FDA's regulatory and monitoring requirements necessary for a quality clinical research. It is a recommended program to provide clinical investigators the skills to recognize safety issues and ethical problems that may compromise the research and the human subjects[73].

The Site Metrics for Study Start-Up project was approved in September 2010. This project has the objective of analyzing timelines for the start-up of phase III multi-center studies from existing datasets, developing a list of data elements to be used to generate standard metrics, initiating a pilot study to prospectively collect metrics on a sample of phase III multi-center clinical trials, and analyzing potential mechanisms for continuous public posting.

# CHAPTER 5

# WEB SOURCES OF CANCER CLINICAL TRIALS

This study is intended for participants with access to the internet in search of information with regard to cancer diseases. As presented in the 2000 CCTS Harris Interactive study, the majority of cancer patients are unaware of ongoing trials. However, cancer patients with a particular interest in receiving information about clinical trials can obtain it from different cancer centers and associations. A web search for national and international cancer organizations may retrieve more than 120 links[74]. Interested individuals may need to search each site until finding the information they are looking for. It can be an overwhelming and frustrating process. The following are descriptions of few web sources that the general public may search for information, interactive tools and literature conveying knowledge and awareness about cancer.

## 5.1 AMERICAN ASSOCIATION FOR CANCER RESEARCH

The American Association for Cancer Research (AACR) is a reputable association founded by scientists at the beginning of this century. Their goal at the time was to investigate and spread the knowledge of cancer. Today their mission is to prevent and cure cancer through research, education, communication, and collaboration. AACR's goal is to accelerate the dissemination of new research findings among scientists, promote science education and training, and advance the understanding of cancer etiology, prevention, diagnosis, and treatment throughout the world[75]. Despite the described responsibilities, to obtain clinical trial information from AACR, a subject

must complete a questionnaire and at the end, it may result in no matches of clinical trials or the match is not appropriate.

## 5.2 AMERICAN CANCER SOCIETY

The American Cancer Society (ACS) with headquarters in Atlanta, Georgia is a community-based voluntary health organization with 900 local offices nationwide. The ACS mission is to provide information about cancer research, education, advocacy, and service. They develop international cancer societies and collaborate with other cancer-related organizations throughout the world.

The ACS website can be accessed from all countries around the world. The web site offers free education accessed by the different type of cancer diseases, prevention and side effects of cancer treatments. Complementary information on how to understand the diagnosis and support programs also can be found in the web site.

It is also an interactive web community service. The service consist in providing access to public forums, health and medical information, book/publications, some personalized features for instance, calendaring, email, to-do lists and bookmarks. The users of the ACS web site may register and create a personal account profile. However, ACS establishes the limits concerning use of the web site, including how long email messages, message board postings are retained, the amount of emails that can be sent or received by an account, the disk space allotted on servers for an account, and the duration for which an account can be accessed in a given period of time[76].

## 5.3 NATIONAL CANCER INSTITUTE

The National Cancer Institute (NCI) is part of the National Institutes of Health (NIH), which is one of the agencies that compose the Department of Health and Human Services (HHS). The NCI is the Federal Government's principal agency for cancer research and training. The NCI coordinates the National Cancer Program, which conducts and supports research, training and dissemination of comprehensive cancer information with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients [77]. They provide online training and education courses for health professionals. The general public and cancer patients can find and browse available results of cancer clinical trials. NCI lists noteworthy clinical trials and provide web-based publications and booklets and DVD educational material in depth of clinical trials. They offer information about treatment, prevention, research being done, statistics and links to other web sources of information for each type of cancer. They also provide the Really Simple Syndicate (RSS) service to deliver web news and other frequently updated materials for interested subscribers. NCI offers a program of unlimited "24 hours phone service" and "live chatting service" concerning cancer topics. The NCI is a reliable educational web center for cancer and cancer clinical trials education.

## 5.4 FDA'S WEBSITE

The Food and Drug Administration Modernization Act (FDAMA) of 1997 established ClinicalTrials.gov as an option for registering approved clinical trials. Among the provisions set in the 2007 FDAAA the clinical trial registration was added as a requirement for individuals or organizations conducting clinical trials[78,79]. The effective date for this final rule was March

2011, as presented in section 4.1.1, requires a statement in the informed consent documents and processes that clinical trial information will be entered into a databank.

The NCI lists approximately 8,000 cancer clinical trials recruiting subjects while ClinicalTrials.gov lists more than 11,500 cancer trials recruiting subjects. The NCI website for clinical trials is not current with all registered studies in ClinicalTrials.gov.

FDA keep evolving and optimizing their web page with the goal of better provide information that assist the general public[80]. While the *News & Events, Public Health Focus, For Consumers, Recalls & Alerts, Spotlight,* provide information of about health in general, *Science & Research* features the information about clinical trials. It contains links to other websites to browse information and regulations about clinical trials for the general public and potential clinical trials participants concerning issues with IC, clinical investigators, IRBs and challenges in protecting human subjects as presented in section 2.4[81]. The FDA provides an online training to teach users how to effectively browse for clinical trials. The training is located within the "The Reference and Web Services" section of the National Library of Medicine® (NLM®) of the National Institute of Health that provides biomedical information for health professionals, scientists, and the general public[82]. The FDA is the agency responsible for advancing the public health by approving modern more effective, safer, and more affordable medicines and by helping the public get the accurate information they need to improve their health[83]. Therefore, other web sources of cancer clinical trials information may not be as reliable as the FDA's web sources. The questions remain: "Is the public aware of these tools?" and "Do they use them to search for cancer clinical trial information".

# CHAPTER 6

# EVALUATION OF PUBLIC USE OF THE FDA's WEB-BASED CLINICAL RESOURCES SURVEY

The intent is to evaluate if participants in this study search the FDA website and their awareness that clinical trials information is provided in the website. Some complementary questions besides demographics were included in the questionnaire.

## 6.1 STUDY METHODOLOGY

The data were collected using an online survey. The survey "Assessment of Public use of the FDA web site" questions are described in Appendix A. The multiple choice questions were answered anonymously. The snowball sampling technique was employed for the data collection.

Different sampling techniques are described in "The Research Process" by Dr. David S. Walonick a retired statistics professor from the University of St. Thomas in St. Paul, Minnesota[84]. The Snowball sampling relies on referrals from initial subjects to generate additional subjects. It is a good procedure to access hidden populations that are potentially threatening, for instance, drug users, men who have sex with men, or homeless subjects. In this study the technique was appropriate to reach a desired sample of cancer patients since the researcher does not have access to this population. The snowball sampling may introduce bias because the technique itself reduces the likelihood that the sample will represent the population.

However, when biases associated with this type of sampling method are analyzed in sufficient details, known levels of precision can be reached[85].

Furthermore, the participants in this study can be classified in sample subsets based on common characteristics shared by the population. Stratified sampling is used when one or more of the stratums or subsets in the population have lower incidence rates relative to the other stratums to reduce the sampling error, as it occurred in this study. Applicable subsets in this study are scientists, cancer patients, physicians, age range, location and gender. The Chi-Square test was used to determine independence between the different subsets of the sample with regard of the subset's tendency to browse the FDA website and subset's awareness that the FDA's website provides cancer clinical trials information. Also, the influence of high rate of female participation in the survey with regards of this subset's tendency of searching cancer information and cancer clinical studies treatments was assessed using the Chi-Square test. The Chi-Square test was performed using Minitab16 software.

The snowball sampling for this study was initiated with the researcher's personal contacts. They were notified by email and requested to forward the survey electronic link to their personal contacts. After this initial interaction, the researcher no longer stays in touch with participants except for a reminder to encourage participation. The survey's electronic link was posted at the social network website Facebook, to be accessed anonymously by the researcher's personal contacts. The link was also posted within Facebook community groups on the topic of cancer. These groups were created by individuals to honor the memory of lost ones and/or to invite the public to share experiences and knowledge in promotion of cancer awareness. The community groups included in this research are "Breast Cancer", "Cancer", "Voices Against Brain Cancer", "Skin Cancer", "American Lung Association's Master the Met", "Brain Cancer Awareness

Support Group" and "Know Cancer." These community groups are publicly available at Facebook.

The survey was carried out using SurveyMonkey™ Professional version software. The software reports the total sample size and the percent relative frequency for each response;

($f_1/n$ *X 100, where* $f_1$*is the frequency of the particular answer and n is the sample size)*

The rate frequency was calculated for sub levels created with conditional or logic questions. Logic questions required a specific answer to move the participant to a different section in the survey.

($f_1/n_i$ *X 100, where* $f_1$*is the frequency in sub- level of the particular answer and* $n_i$ *is the sample size in the sub-level)*

Logic questions were used to filter the sample of "physicians" and "cancer patients" from non-applicable questions. Logic answers were used to either continue or skip to the next question. Logic question progression is not to be confused with "Skipped This Question", which is one of the multiple choice answers provided to protect the participants' welfare.

Figure 1 presents an overview of the questions in the survey using "physician" and "cancer patients" answers for logic questions. The question in the box is an example of the set of questions for the respective sub-group. A "physician" that is also a "cancer patient" went through all the questions formulated for this survey.

Figure 1. Logic Questions Path

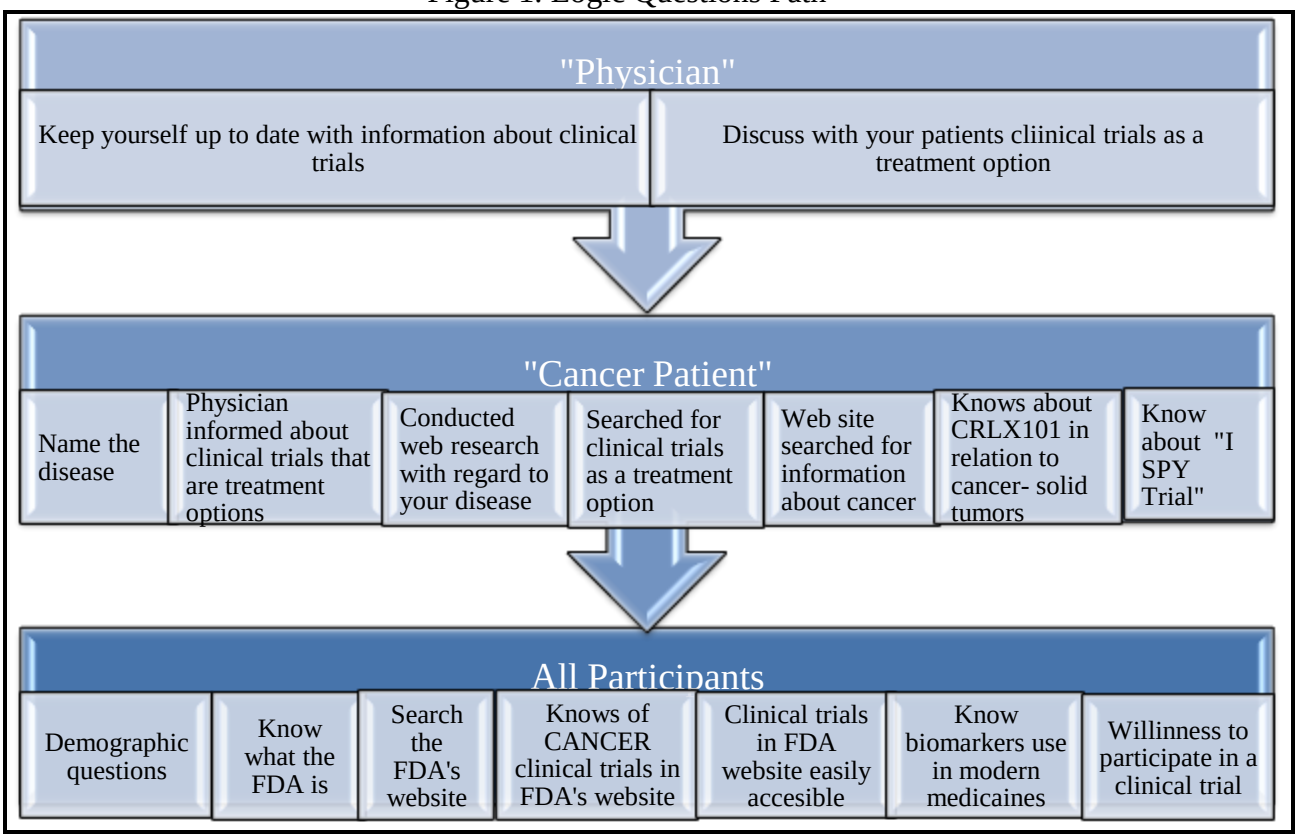
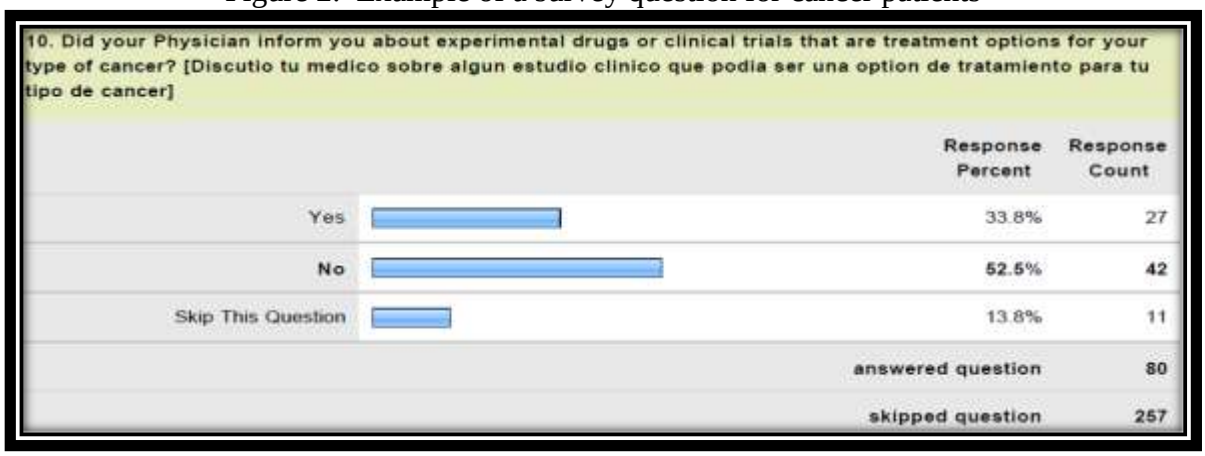



Figure 2 is an example of a question formulated for participants that are “cancer patient”. The figure shows that 11 cancer patients who participated in the survey opted not to answer the question, and 257 participants reported as “skipped question” did not meet the logic question meaning that they were not cancer patients.

Figure 2. Example of a survey question for cancer patients



10. Did your Physician inform you about experimental drugs or clinical trials that are treatment options for your type of cancer? [Discutio tu medico sobre algun estudio clinico que podia ser una option de tratamiento para tu tipo de cancer]

| | Response Percent | Response Count |
|---|---|---|
| Yes | 33.8% | 27 |
| No | 52.5% | 42 |
| Skip This Question | 13.8% | 11 |
| answered question | | 80 |
| skipped question | | 257 |

Two ongoing clinical trials registered in ClinicalTrials.gov, CRLX101 and I SPY 2 Trial, were included in the survey to evaluate awareness of cancer patients about current cancer clinical trials. CRLX101 (NCT00333502) was initiated in May 2006 with expected completion date in August 2011. I SPY Trial (NCT01042379) was initiated in March 2010 with expected completion date in November 2014. Recruitment for these studies was current for several months previous this research study to give an opportunity for participants interested in clinical trials to learn about them. These studies were selected to represent current cancer trials because they were designed in accordance with new scientific technology and with a modern clinical trials design, respectively, to protect the safety of the subjects. CRLX 101 is a nanotechnology that appears to deliver the toxic drug directly to the tumor with low toxic exposure to the patient. I SPY Trial is a collaborative experimental treatment using the patient's medical and biological information to tailor personalized treatment for breast cancer. These could become innovative therapies if the safety and effectiveness is demonstrated.

The data for this study was imported from SurveyMonkey$^{TM}$ to be analyzed using Microsoft Excel.

The survey determined:

- Whether a physician ever mentioned clinical trials as a treatment option.
- Whether patients are interested in clinical trials.
- Websites searched by cancer patients for cancer information.
- Awareness of the FDA's website as a source of information for cancer clinical trials.
- Cancer patient's awareness of IT-101 and I SPY Trial.
- Willingness to participate in a clinical trial knowing that it could be a treatment option.

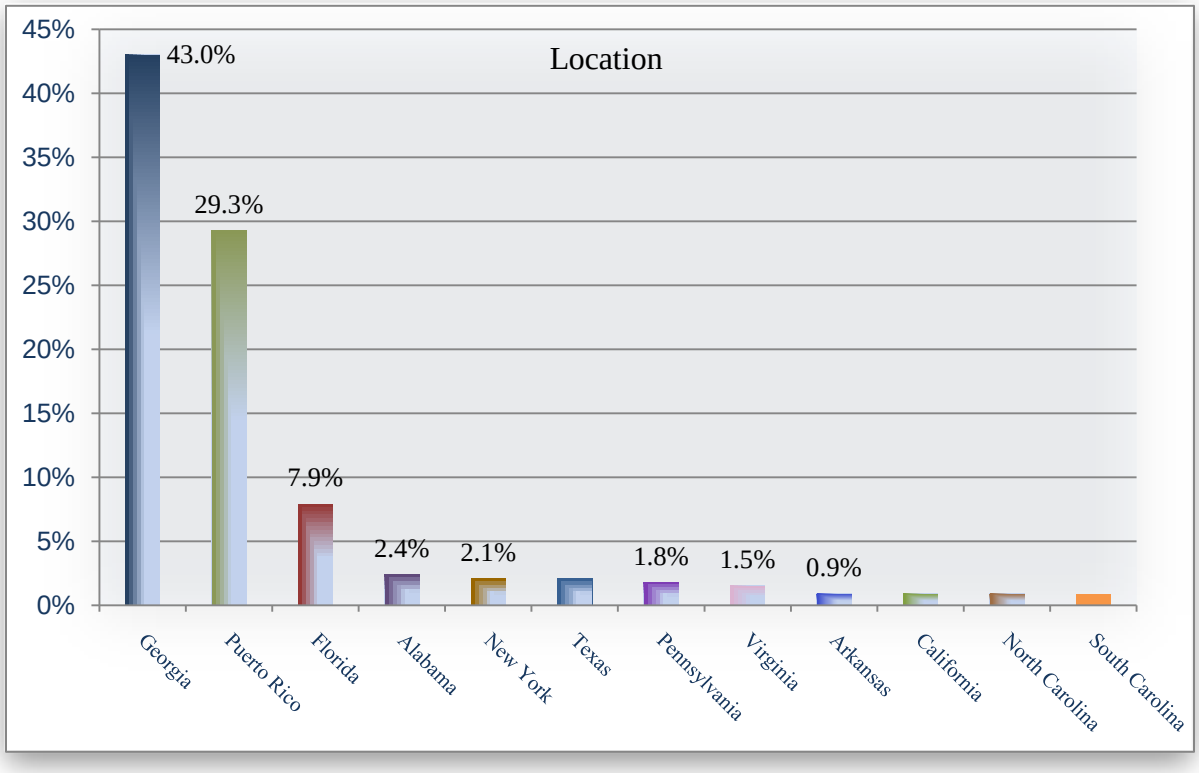
## 6.2 RESULTS

The survey "Assessment of Public use of the FDA web site," with particular interest to determining if clinical trials information was accessed from the FDA's web site, was conducted from November 2010 to March 2011 with 337 online participants, presented in Appendix B. Out of a total of 337 respondents 91.7% completed the survey. The survey was designed to also determine the awareness of the participants about biomarkers used in medicine and their willingness to participate in clinical trials. Table 1 provides the demographic information of the participants. Women represented almost 60% of the participants, an inequality of gender participation as presented in some studies where females have a higher tendency than men to participate in online surveys[86]. The majority of the sample participants were within the age range of 31-50years old. Also, 24.9% of the total sample was cancer patients, cancer survivors, or cancer patient care providers. Cancer patients, cancer survivors, and cancer patient care provider who participated in this study will all be referred to as cancer patients. A high rate of participants was observed from Georgia, Puerto Rico and Florida, and this data appears in Figure 3. The unbalanced relative frequency in each group could be related to the sampling technique used to recruit the participants.

Table 1. Description of the sample

| Age Range | Total | Relative Frequency |
|---|---|---|
| > 18 | 3 | 0.9% |
| 18-30 | 23 | 6.8% |
| 31-50 | 215 | 63.8% |
| 50-100 | 95 | 28.2% |
| Gender | | |
| Male | 132 | 39.8% |
| Female | 198 | 59.6% |
| Cancer Patients | 81 | 24.9% |
| Education | | |
| < High School | 6 | 1.8% |
| High School | 45 | 13.8% |
| College Degree | 274 | 84.0% |

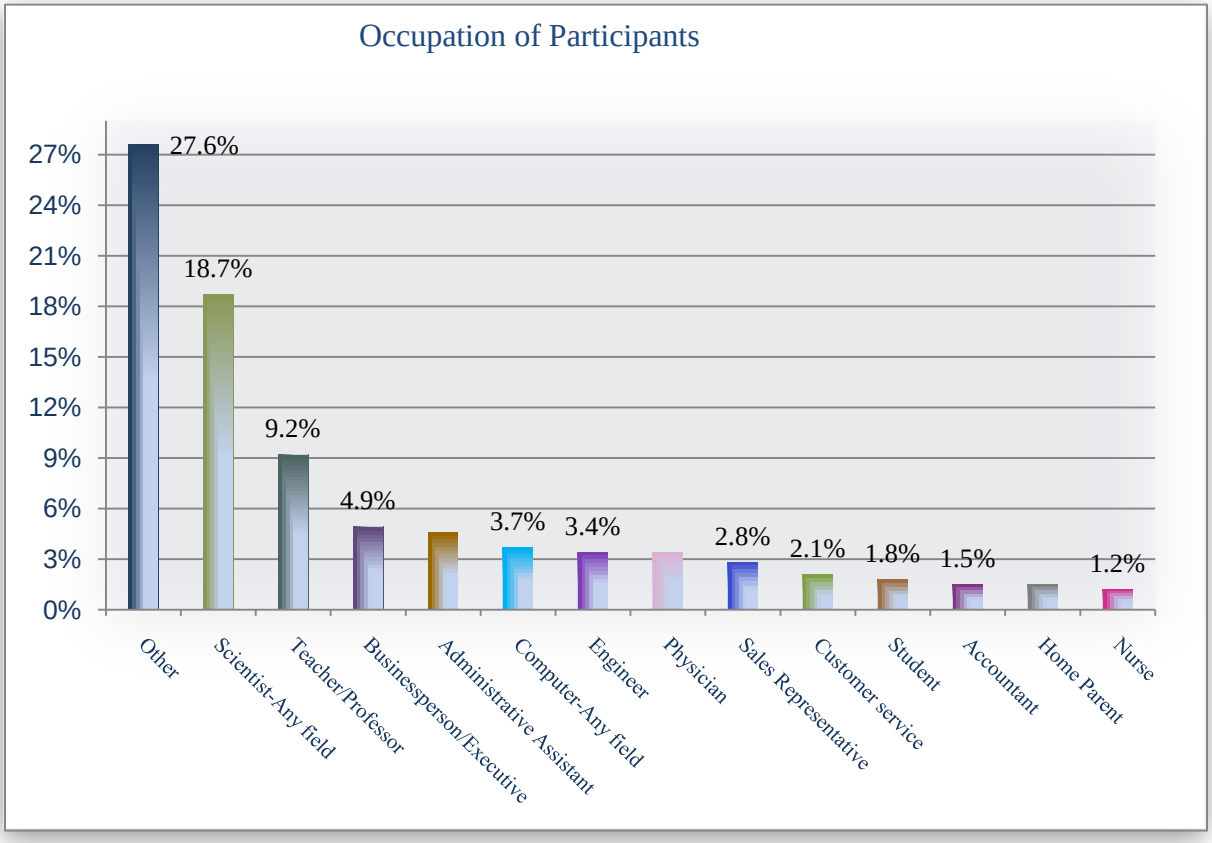
Figure 3- Geographic Location




Other population not shown- were 0.3% and 0.6% living in Ohio, Oklahoma, Massachusetts, Missouri, and Montana.

Most of the participants, 84.0%, are people who completed a college degree, while 27.6% have un-identified occupations, 18.7% are scientists, 9.2% are teachers, and 3.7% are physicians, presented in Figure 4.

Figure 4- Participants Education




Other is the addition of multiple occupations not specified

Physicians were asked if they are current with information about clinical trials and if the information is discussed with patients to encourage them to consider clinical trials as a treatment option. Out of the twelve physicians who participated, 66.7% are aware of current clinical trials, only 37.5% or 3 physicians of those aware of clinical trials information discuss trials with patients, 25.0% (or 2 physicians) do not discuss clinical trials with their patients and 12.5% of those "up to date physicians" (1 physician in this study) would discuss the trial with patients if the clinical trials concerns innovative medicine. The data obtained from physicians is presented in Table 2.

Table 2-Physicians Data

| Awareness of current clinical trials | Total | Rate Frequency |
|---|---|---|
| Yes | 8 | 66.7% |
| No | 4 | 33.3% |
| Discuss Clinical Trials with patients | Total | Rate Frequency |
| Yes | 3 | 37.5 % |
| If Innovative Medicine | 1 | 12.5 % |
| No | 2 | 25.0% |
| Skipped Question | 2 | 25.0% |

Cancer patients were asked to share their experience with regard to their doctors informing them about experimental treatment, and their preferences conducting research with regard to the diseases. Cancer patient participants were assessed for awareness of "CRLX101" and "I SPY Trial, two experimental therapies, discussed in section 2.5. Table 3 presents the cancer patients' responses. The doctors of 33.8% cancer patients discussed clinical trials with them; 59.0% of cancer patients interested in additional information about their disease conducted their own search; from those, 37.8% were interested in finding clinical trials information. This 37.8% represents 20.6% or 17 cancer patients who participated in this survey performed their own search of information about the disease. Approximately 90% of all cancer patients responding the survey, without differentiating whether or not they were interested in additional cancer information or cancer clinical trials, were un-aware of both CRLX101 and I SPY Trial.

Table 3- Cancer Patients Data

| Physician informed them about clinical trials as treatment options | Total<br>81 | Rate Frequency |
|---|---|---|
| Yes | 27 | 33.8% |
| No | 42 | 52.5% |
| Skipped Question | 11 | 13.8% |
| Conducted search of disease | | |
| Yes | 46 | 59.0% |
| No | 24 | 30.8% |
| Skipped Question | 8 | 10.3% |
| Searched for clinical trials as a treatment option | | |
| Yes | 17 | 37.8% |
| No | 27 | 60.0% |
| Skipped Question | 1 | 2.2% |
| Awareness of "IT-101 or CRLX101" | | |
| Yes | 2 | 2.6% |
| No | 70 | 89.7% |
| Skipped Question | 6 | 7.7% |
| Do you know what "I SPY Trial" | | |
| Yes | 6 | 7.8% |
| No | 69 | 90.8% |
| Skipped Question | 1 | 1.3% |

The Chi-Square test is a statistical method to test whether two variables are independent or homogeneous. The test examines whether knowing the value of one variable helps to estimate the value of another variable.

*For:* A null hypothesis $H_0: \mu_1 = \mu_2$

where: $H_0$ = the null hypothesis

$\mu_1$ = the mean of female cancer patient

$\mu_2$ = the mean of male cancer patient

The Chi-Square test was conducted to determine independence among gender of cancer patients with regard to frequency searching for cancer information and searching for cancer clinical trials as a treatment option. A p-value of less than 0.05, most commonly used to "reject the null hypothesis" or reject that the mean of the subsets are equal and the difference is "statistically

significant" was applied for these comparisons. A p-value greater than 0.05 was used to "do not reject the null hypothesis" and to say that the difference is "not statistically significant".

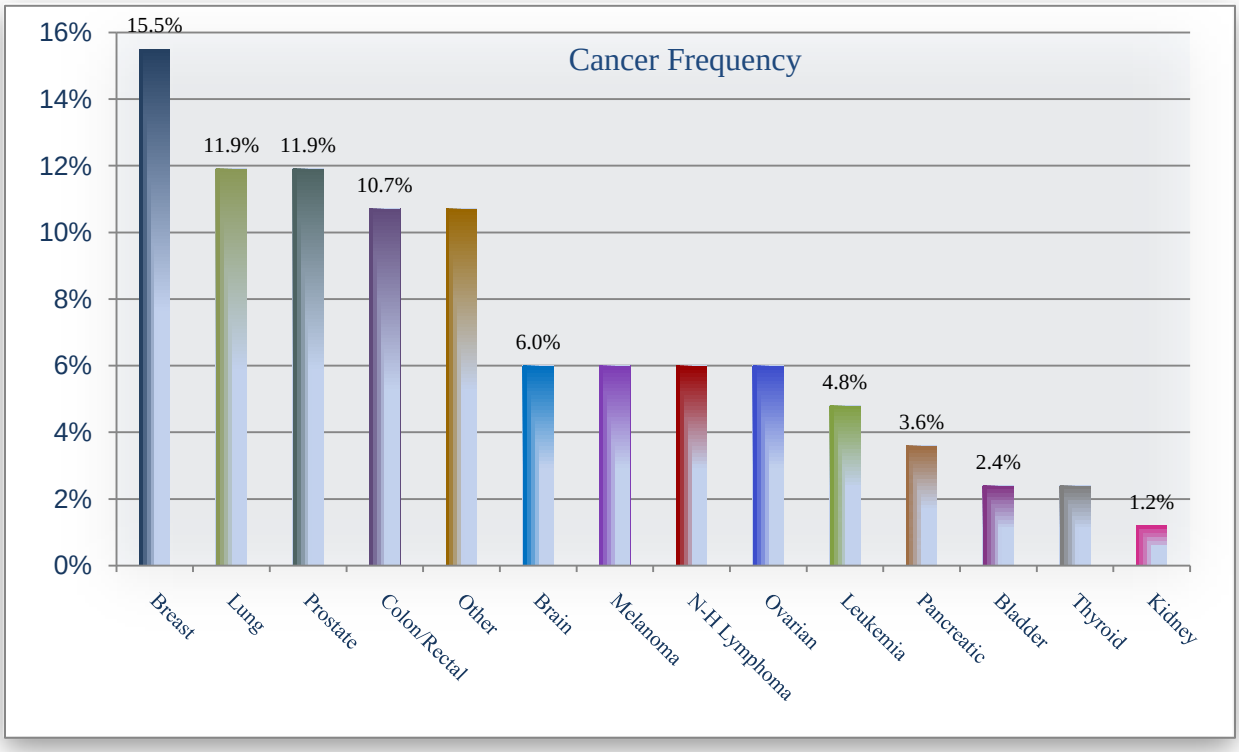
Based on gender, the Chi-square p-value determined for tendency of web-search information about cancer and cancer clinical trials was 0.41 and 0.07, respectively is captured in Appendix C. Therefore, we do not reject that the mean of male cancer patient and female cancer patient is equal and the difference between the gender searching for cancer information and cancer clinical trials is not statistically significant, regardless that the female cancer patients represented 68% as presented in table 4.

Table 4- Cancer Patients Searching for Cancer Information by Gender

| | Total | Female | Male | |
|---|---|---|---|---|
| Total | 81 | 55 (68%) | 26 (32%) | p-value |
| Conducted search of disease | | | | |
| Yes | 46 | 28 | 18 | 0.41 |
| No | 24 | 17 | 7 | |
| Searched for clinical trials as a treatment option | | | | |
| Yes | 17 | 7 | 10 | 0.07 |
| No | 27 | 19 | 8 | |

Cancer patients disclosed the type of their disease, and this information appears in Figure 5. Breast cancer, lung cancer, prostate, and colon/rectal cancer were the most frequent types of cancer in this studied sample. These are the same four most frequent types of cancer referenced by the National Cancer Institute statistics [87].

Figure 5- Cancer frequency

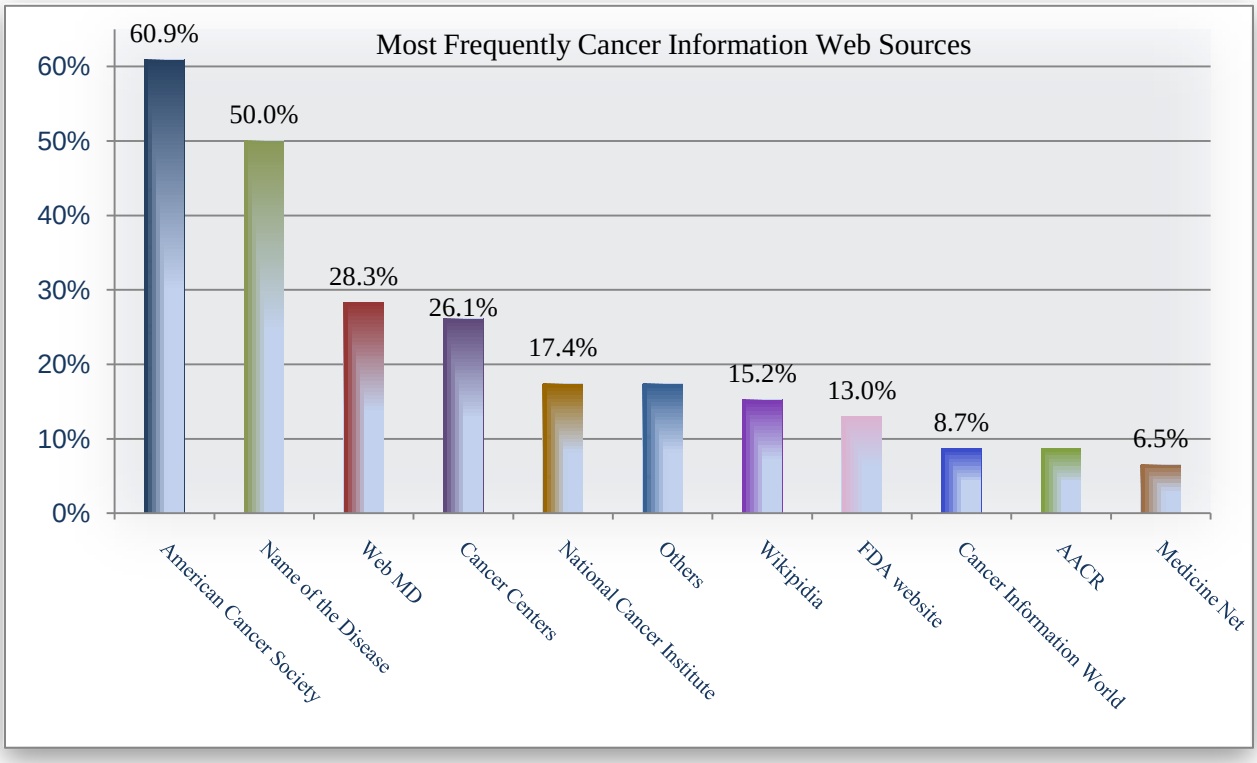



Other - the addition of multiple type of cancer not specified

Cancer patients also revealed the web sources they use to search for cancer information. This data is presented in Figure 6. The American Cancer Society is the most frequently visited website, and it is preferred by 60.9% of cancer patients participating in this survey. It is followed by 50.0% who just search for the type of the disease, 28.3% who search WebMD, and 26.1% who search cancer centers such universities and hospitals websites. Surprisingly, the government supported entities--The NCI and FDA --are not within the most frequented web sites to get cancer information. Unexpectedly, Wikipedia is visited to obtain cancer information more often than the FDA's web site with 15.2% and 13.0% frequency, respectively.

Individual participants mentioned Scirus[88], a web search engine developed especially for scientists, researchers, and students. They also made referenced to Medicina Alternativa[89], a service from the National Library of Medicine with links to National Cancer Institute in Spanish.

Figure 6- Most Frequently Searched Web Sources For Cancer Information




The section of the survey to evaluate the general public awareness about FDA and FDA's website browsing tools for cancer clinical trials was common for all participants. Table 5 presents the results of the FDA awareness assessment. The sample knows, trusts, and thinks that the FDA is working toward protecting the public health and approving new medical products. However, as many as 67.8% of the participants do not search the FDA's website, and 82.1% are unaware that FDA provides information about cancer clinical trials. It seems to be easy to access the clinical trial information from the FDA web site only for those who are aware that the information is provided. It was confirmed by having only 6.3% of participants aware that more than 350 cancer or neoplasms studies are currently listed in the FDA's clinical trials databank. These data supported the researcher's question for this study:  that people are not aware of

browsing tools for information related to clinical trials of cancer diseases in the FDA's website. Information that could benefit cancer patients is not being accessed through the FDA's website.

Table 5- Awareness of FDA website

| | Total | Relative Frequency |
|---|---|---|
| Know what is FDA | | |
| Yes | 309 | 96.6% |
| No | 11 | 3.4% |
| Skipped Question | 0 | 0 |
| Think FDA is doing their job to protect the general public health | | |
| Yes | 215 | 69.6% |
| No | 79 | 25.6% |
| Skipped Question | 15 | 4.9% |
| Trust FDA approval decisions | | |
| Yes | 207 | 67.2% |
| No | 88 | 28.6% |
| Skipped Question | 13 | 4.2% |
| Search the FDA website | | |
| Yes | 94 | 30.6% |
| No | 208 | 67.8% |
| Skipped Question | 5 | 1.6% |
| Does FDA's website provides information about CANCER clinical trials | | |
| Yes | 32 | 10.4% |
| No | 11 | 3.6% |
| Do not know | 252 | 82.1% |
| Skipped Question | 12 | 3.9% |
| CANCER clinical trials in FDA website easily accessible | | |
| Yes | 25 | 78.1% |
| No | 6 | 18.8% |
| Skipped Question | 1 | 3.1% |
| How many cancer studies are listed in the FDA website | | |
| >350 studies | 2 | 6.3% |
| None | 1 | 3.1% |
| Do not know | 25 | 78.1% |
| Skipped Question | 4 | 12.5% |

The physicians, cancer patients, scientists, participants in the age range of 31-50 years old and gender subsets could impact the homogeneity of the sample in terms of tendency to browse the FDA website and awareness of FDA's website as a source of information for cancer clinical trials.

The Chi-Square test was conducted again to test whether two variables are independent or homogeneous among physicians, scientists, cancer patients, gender, 31-50 age range and location subsets with regard of searching the FDA web site and awareness that FDA's website provides cancer clinical trials information. Using the same principle as above:

$H_0: \mu_1 = \mu_2$ such as $\mu_1$ = the mean of Non-Scientist $\mu_2$ = the mean of Scientist

A p-value of less than 0.05, to reject that the mean of the subsets are equal and the difference is "statistically significant" was also applied for these comparisons. If the p-value was greater than 0.05 was used to "do not reject the null hypothesis" and that the difference is "not statistically significant". Table 6 shows a summary of the observed frequencies for the different sample subsets. The Chi-Square interpretation was conducted based on the summarized data in Table 7, presenting p-values for each sample subsets and Table 8, presenting the Chi-Square tabulated data for each sample subset that showed to be statistically significant with p-value less than 0.05 from the Chi-Square test.

Table 6- Frequency of Sample Subsets

| | Total | Physicians | Scientists | Cancer Patients | Female | Age 31-50 years | Location Georgia Florida Puerto Rico |
|---|---|---|---|---|---|---|---|
| Total | 309 | 12 | 61 | 81 | 198 | 215 | 263 |
| Search the FDA website | | | | | | | |
| Yes | 94 | 8 | 43 | 25 | 49 | 69 | 73 |
| No | 208 | 3 | 15 | 45 | 127 | 127 | 168 |
| Awareness FDA's website provides clinical trials | | | | | | | |
| Yes | 32 | 2 | 14 | 7 | 14 | 20 | 27 |
| Do not know | 252 | 8 | 40 | 55 | 154 | 159 | 207 |

Table 7- Chi-Square P-value for the different Sample Subsets

| | Physicians | Scientists | Cancer Patients | Gender | Age 31-50 years | Location Georgia Florida Puerto Rico |
|---|---|---|---|---|---|---|
| Search the FDA website p- value | <0.05 | <0.05 | 0.38 | 0.13 | <0.05 | 0.54 |
| Awareness FDA's website provides clinical trials information p- value | 0.31 | <0.05 | 1.00 | 0.06 | 1 | 1 |

Table 8- Chi-Square Expected and Observed counts for the different Sample Subsets with p-value less than 0.05

| **Search the FDA website** | | | | | | |
|---|---|---|---|---|---|---|
| | Physician | Non-Physician | Scientist | Non-Scientist | Age Range 31-50 years | Age Range 18-30 51-100 years |
| No Expected | 8 | 205 | 40 | 168 | 135 | 73 |
| Observed | 3 | 200 | 15 | 193 | 127 | 81 |
| Yes Expected | 3 | 91 | 18 | 76 | 61 | 33 |
| Observed | 8 | 86 | 43 | 51 | 69 | 25 |

| **Awareness of Clinical Trials Listed in the FDA website** | | | |
|---|---|---|---|
| | | Scientists | Non-Scientists |
| No | Expected | 48 | 204 |
| | Observed | 40 | 212 |
| Yes | Expected | 6 | 26 |
| | Observed | 14 | 18 |

*Physicians*

The Chi-Square data for physicians is presented in Appendix D. The p-value for frequency of physicians searching the FDA website is less than 0.05, therefore we reject that the mean of physicians searching the FDA website is equal to the mean of non-physician participants. The observed count for a physician searching the FDA website is higher than the expected count, while the observed count for a non-physician is lower than the expected. Thus, a physician shows higher tendency to search the FDA website than a non-physician participating

in this study. The expected count is less than 5, however the Fisher's exact test confirmed the p-value is less than 0.05.

The p-value for physician's awareness of clinical trials listed in the FDA website is greater than 0.05, therefore we do not reject that the mean of these subsets is equal and the difference between a physician and a non-physician participating in this study is not statistically significant for awareness of clinical trials listed in the FDA web site.

*Cancer Patients*

The Chi-Square data for cancer patients is presented in Appendix E. The p-value for cancer patients frequently searching the FDA website and for awareness of clinical trials listed in the FDA web site is greater than 0.05, therefore we do not reject that the mean of this subset is equal to the rest of the sample and the difference between the subset and the rest of the sample is not statistically significant.

*Scientists*

The Chi-Square data for scientists is presented in Appendix F. The p-value for scientists searching the FDA website is less than 0.05, therefore scientists and non-scientists have different tendencies to search the FDA's website. The observed count of scientists searching the FDA website is higher than the expected count and for a non-scientist the observed count is lower than the expected. Thus, scientists have higher tendency to search the FDA web site than non-scientists that participated in this study.

The p-value for scientist's awareness that FDA's website provides cancer clinical trials information is less than 0.05, therefore we reject that the mean of scientist and the rest of the

sample awareness of clinical trials listed in the FDA website is equal and therefore, scientists and non-scientists have different awareness that FDA's website provides cancer clinical trials information. Because the observed count for scientists' awareness is higher than expected count and for non-scientists the observed count for awareness is lower than expected count we conclude that scientists have higher awareness that FDA's website provides cancer clinical trials information than non-scientists.

*Gender*

The Chi-Square data for gender is presented in Appendix G. The p-value for female frequently searching the FDA website and for awareness of clinical trials listed in the FDA web site is greater than 0.05, therefore we do not reject that the mean of the female subset is equal to the male subset sample and the difference between female and male is not statistically significant.

*Age range of 31-50 years old*

The Chi-Square data for people in the age range of 31-50 years old is presented in Appendix H. The p-value for participants in this age range searching the FDA website is less than 0.05; therefore these subjects and the rest of the participants have different tendencies to search the FDA's website. For participants in the age range of 31-50 years old, the observed count of frequency searching the FDA web site is higher than the expected count. For participants within 18-30 and older than 50 years old of the sample the observed count is lower than the expected count being less likely to search the FDA website. Thus, participants in the age range of 31-50 years old showed higher tendency to browse the FDA website than the rest of the participants in this study.

The p-value for participants in the age range of 31-50 years old for awareness that FDA's website provides cancer clinical trials information is greater than 0.05, therefore we do not reject that the mean of the participants in the 31-50 years old age range subset and the mean of the rest of the participants for awareness of clinical trials listed in the FDA website is equal and the difference between the age subsets is not statistically significant.

*Location*

The p-value for participants from Georgia, Florida and Puerto Rico frequently searching the FDA website and for awareness of clinical trials listed in the FDA web site is greater than 0.05, therefore we do not reject that the mean of participants in these locations is equal to the rest of the participants in different areas of USA and the difference among participants from different locations is not statistical significant. The Chi-Square calculations are presented in Appendix I.

These data show that physicians, scientists and participants in the age range of 31-50 years old subsets might exerted influence over the 30.6% of the sample who has the tendency to search the FDA's website and scientists might exerted influence over the 10.4% of the sample that are aware of cancer clinical trials information listed in the FDA's website.

An overview assessment of biomarker awareness was conducted with all participants, because of the advances in medicine using biological molecules (biomarkers) to diagnose or better treat a disease. The results of the general population's awareness about biomarkers are presented in table 9. This data shows that half of the participants are informed about biological markers, and

62.5% of those with some knowledge about biomarkers are familiar with how these biological tools are being used in modern medicine.

Table 9- General Knowledge of Biomarkers

| | All sample population | |
|---|---|---|
| Know about biomarkers | Total | Rate Frequency |
| Yes | 151 | 47.6% |
| No | 159 | 50.2% |
| Skipped Question | 7 | 2.2% |
| Know how biomarkers are use in modern medicine | | |
| Yes | 95 | 62.5% |
| No | 56 | 36.8% |
| Skipped Question | 1 | 0.7% |
| How did you learn about biomarkers | | |
| Yes | 7 | 4.6% |
| No | 131 | 86.8% |
| Skipped Question | 13 | 8.6% |

This study *Evaluation of Public use of the FDA's Website Clinical Resources*, was concluded by evaluating the willingness of all participants to consider participation in clinical trials knowing that experimental therapy could be an alternate treatment. In general the participants are not willing to participate in clinical trials. Only 21% of cancer patients and 16% of the rest of the participants in this study would opt to participate in clinical trials. However, 41% of cancer patients and 55% of the rest of the participants in this study might consider the option if more information is provided. The results of cancer patients and the general public's interest in participating in clinical trials are presented in Figures 7 and 8.

Figure 7- Willingness of Cancer Patients to Participate in Clinical Trials

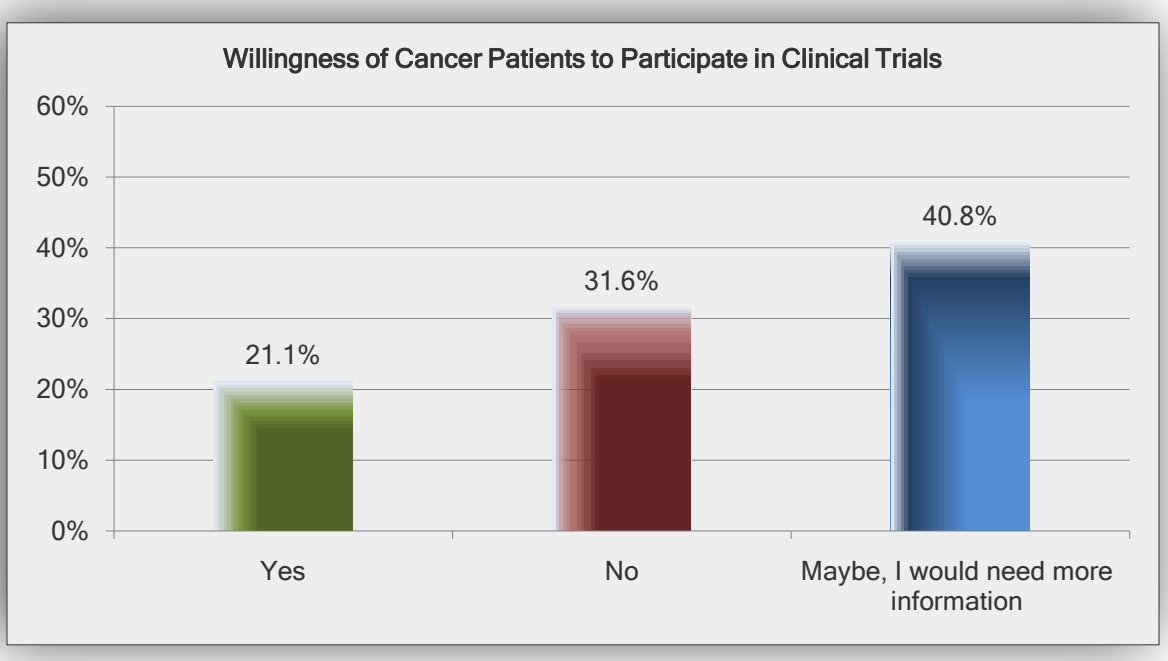
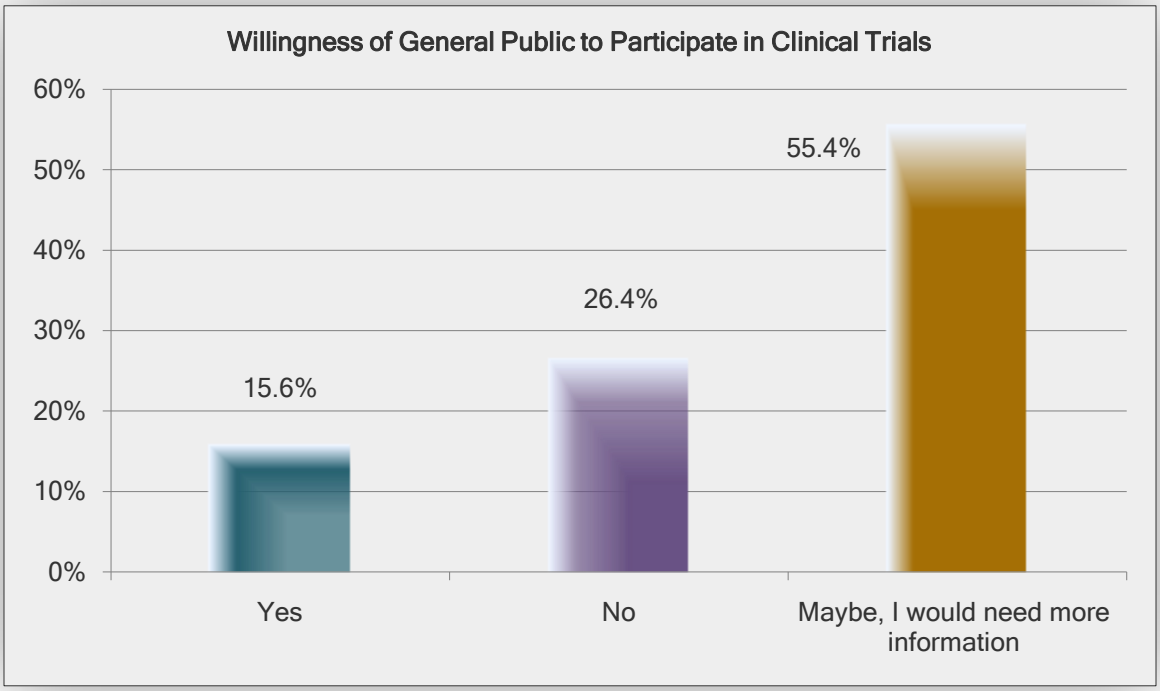



Figure 8- Willingness of General Public to Participate in Clinical Trials



## 6.3 ADDITIONAL COMMENTS

### 6.3.1 RELEVANT COMMENTS FROM PARTICIPANTS

Taken from Appendix B:

"I tried to research clinical trials for my mother, who had lung cancer, & did not have much luck. A friend is now in a clinical trial for prostate cancer, as a last resort. It's giving him more time with a good quality of life & hopefully will help others in the future."

"Many of my friends have been diagnosed with cancer and some have died. I sure would like to know the FDA was doing all it could do to come up with a cure."

"When you are diagnosed with cancer even if you are a doctor you may not want to know the alternatives of treatment depending if you are in denial or depressed."

"I have not developed any cancer affliction so far. Although now I devote my life to music, I earned a PhD in chemistry and worked in the Regulatory Affairs field in the Pharmaceutical Industry and am very aware of the role of the FDA. Sadly, I have lost friends to cancer. More needs to be done."

"The community needs more education about eating habits and life style that lower the risk to develop cancer." (Translated from Spanish)

"It would be a good idea if FDA provides a web-link for information about new scientific advances about specific diseases." (Translated from Spanish)

"I nursed my sister who had pancreatic cancer. We suspect that she passed away due to the chemotherapy medications rather than the cancer. I don't know if they were experimental drugs." (Translated from Spanish)

"My experience as a friend of few cancer victims/cancer survivors is that the medicine field is extremely politicized, and in many cases because of this, many are falsely diagnosed or diagnosed to late where so little can be done."

"If I have the opportunity I would participate in a clinical study to help advancing research against cancer diseases". (Translated from Spanish)

"I am thankful for those who do participate in human clinical trials, but I would not be one of them unless I had an incurable disease and was desperate to try anything".

"I experienced cancer with one of my parent years ago. The treatment given was low radiation for 6 weeks after diagnosis. A more aggressive approach, example surgery, was not recommended by the doctor as the parent was advanced in age. The radiation treatment did not have any effect on the cancer. It sapped my parent energy and quality of life. Eventually excruciating pain was experienced and morphine had to be administered. Death occurred after 9 months of the first diagnosis."

"I was immediately referred to an oncology surgeon and followed his advice/directions. Thankfully all of my cancer was removed and it had not spread to my lymph nodes as was suspected".

"The Simon Cancer Center at the IU Med Center in Indianapolis is the BEST".

"I'm Psychotherapist and I haven't work with this type of patients but I will love to work with them. Thanks!!!"

"I had surgery for colon cancer in 1991. About 1 foot of colon was removed. The malignant tumor was slow-growing and about 4.5 cm. in diameter. Nine or 10 nearby lympth nodes were also removed. I have been free of cancer since the operation. Chemotherapy treatment was used after the surgery."

"I didn't have cancer, but all my mother family had suffered cancer. My grandma (ovarian cancer), my grandpa (throat cancer); my grandma sister (leukemia), etc."

"I have my brother with skin, and colon cancer in jail, where I know that he won't receive the best care for his condition. My mother in law is a cancer survival. Thanks"

"I really think that the cure for cancer had been discovered, but something is hiding".

## 6.4 LIMITATIONS OF THE RESEARCH DESIGN

The snowball sampling technique utilized in this study to recruit subjects from the initial participants gaining participation of cancer patients was adequate. The physician subset was under represented and the location of participants mostly represents the southeast and Puerto Rico. Therefore, the recruiting process should be enhanced by approaching cancer organizations in most states possible using a direct approach. Extending the time to collect response and

providing some compensation for the time spent may increase the participation of all subsets at more regions.

The use of only two current cancer clinical trials, IT-CRLX101 and ISPY, is too limited to thoroughly assess the awareness of cancer patients regarding cancer trials. More in-depth questions should be developed to gain more accurate data.

## 6.5 DISAVANTAGES OF THE STUDY

This research study was conducted as an online survey where honesty from the participants is essential to reduce bias.

- Opportunity for participants to complete the survey multiple times.
- Participants may feel that they are wasting their time and may not take the time to read/assess the question before answer
- Participants may guess the answers to please the researcher.

This study was limited to people with computer and internet access. There is no interaction between the researcher and the participants to clarify the questions if needed. This survey provides an answer to "skip the question" for the benefit of the participants to sensitive questions, which increase the chance for missing or get incomplete data.

The survey included an overview of medicine doctors with limited participation. It should be taken in consideration recruiting larger sample of physicians and if they are cancer patient themselves.

This survey did not differentiate between cancer patients and the care giver of a cancer patient. It was assumed that the majority of this subset is really cancer patients and that all in

the subset would be equally interested in searching information and clinical trials about the disease.

## 6.6 DISCUSSION

As many as 67.8% of the participants do not search the FDA's website and 82.1% are unaware that FDA provides information about cancer clinical trials.

The American Cancer Society, the most frequently visited web source selected by 60.9% cancer patients that participated in the study. More than 65% of the cancer patients browse cancer information by typing the name of the disease and searching within Wikipedia. This practice increased the probability of discovering clinical information such as the cancer research study at the Hutch, The Jessie Helsinger death and the Melanoma Vaccine public reports addressing conflict of interest in cancer clinical trials described in section 2.4, causing fear in potential participants of becoming instruments for experimentation expressed in the CCTS Harris Interactive Survey as one of the reason for low participation by cancer patients in clinical trials presented in section 3.2.

Only 13% of the cancer patients browse the FDA web site. This is a reduced opportunity for those most in need to learn about the modernization of running clinical trials described in the CPI and BIMO FDA's programs. Awareness about FDA's programs to increase the protection of the human subjects participating in experimental therapies presented in section 4.1, might increase trust and ease fear in potential participants.

Almost 32% of cancer patients and 26% of general public participating in this study are not willing to participate in clinical trials. However, 40% of cancer patients and 55% of general public participant would consider the option provided more information. It is essential to conduct cancer clinical trials to achieve advances against the cancer diseases. To expedite to

the access of cancer patients to new therapies is necessary to have more involvement in cancer clinical trials as discussed in section 3.1.

A participant mentioned that it is difficult to find clinical trials. Indeed, the search for cancer clinical trials may not be easy. For instance a Georgian breast cancer patient interested in a clinical trial similar to I SPY TRIAL would get that the I SPY TRIAL is number 65 out of 96 studies searched as "breast cancer and Georgia and recruiting volunteers" in the ClinicalTrials.gov databank. However, by searching as "breast cancer and Georgia and recruiting volunteers and biomarkers" will find that I SPY TRIAL is the second study of 19 listed in the ClinicalTrials.gov databank. This supports the participant's comment about difficulty searching for trials; the individual should have some familiarity or awareness about the study being searching for.

About 50% of the sample is aware about biological markers and 62.5% of those with some knowledge about biomarkers are familiar with how these biological tools are being used in modern medicine.

## 6.7 CONCLUSIONS

This study provides background information supporting that the FDA keeps striving for the welfare of the American consumer by designing strategies and programs to protect the human subjects and to expedite the approval of new and modern therapies. This information is available to the public through their website. Also, the registration of all clinical trials must be through the FDA. The purpose of this research study was to assess whether or not the general public browse the FDA's website and to determine the awareness about FDA's website providing browsing tools to get information about cancer clinical trials. The "Assessment of Public use of the FDA

web site" showed that as high as 68% of the participants do not browse the FDA website and 82% are unaware that the FDA provides cancer clinical trials information. Physicians, scientists and people in the age range of 31-50 years old search the FDA's website more frequently than the rest of the participants in this study, affecting the 31% who has tendency to search FDA website's information. Scientists have higher awareness of clinical trials information listed in the FDA's website impacting the 10% awareness among the participants in this study.

Based on the limitation of using only two current cancer clinical trials; this study shows that 90% of all cancer patients who participated are unaware of CRLX-101 and I SPY Trial suggests that cancer patients may be unaware of similar experimental therapies to that could be of their benefit.

Almost 21% of cancer patients web-search information about clinical trials and 40% of cancer patients participating in this study are willing to consider participation in clinical trials if more information is provided, support that there is a great need to provide cancer patients higher awareness of appropriate cancer clinical trials to gain more involvement.

In general there was higher female and higher female cancer patients than male participating in this study. However, the impact of gender with regard to search for cancer information, cancer clinical trials, browsing the FDA website and awareness of clinical trials listed in the FDA website is not statistically significant.

The American Cancer Society was the most frequently visited website, selected by 61% cancer patients that participated in the study. More than 50% of the cancer patients browse cancer information by typing the name of the disease and 15% search within Wikipedia. Only 13% of the cancer patients browse the FDA web site.

With 1,500 patients dying of cancer every day and only 3% participating in trials, it is critical that the population besides scientists, learn about the evolving FDA's strategies to protect the subjects rights accessible through their website and about ClinicalTrials.gov to find newly approved clinical trials. The general public could use ClinicalTrials.gov as a tool to find out if they would be a potential candidate to participate in a cancer clinical trial for promising therapies listed in the databank.

## 6.8 RECOMMENDATIONS

Based on the research conducted, to better enable practitioners and cancer patients to identify appropriate clinical trials as a course of treatment, the following recommendations are offered:

1. Add hyperlinks to websites most frequented in this study to search for cancer information.
    a. The FDA's Clinicaltrial.gov databank has the listing of all registered clinical trials. The FDA's website needs a hyperlink to the ClinicalTrials.gov online training located in the National Library of Medicine® and a hyperlink to the NCI phone and live online chat service.
    b. The NCI offers a 24 hours phone service and live help online chat service for immediate help answering questions about cancer. The NCI's website needs a hyperlink to FDA's ClinicalTrials.gov.
    c. The American Cancer Society (ACS) was the most frequently visited cancer related website. The ACS website should add a hyperlink to FDA's Clinicaltrial.gov and a hyperlink to NCI phone and live online chat service.

2. According to the study Wikipedia is a more popular source of cancer information than the FDA's website. Wikipedia could be a source to increase awareness of cancer clinical trials as a treatment opportunity for patients. An article should be posted in Wikipedia with the purpose of presenting the need to advance cancer patients' involvement in clinical trials, and to provide opportunity to access the "NCI phone and live online chat service", "ClinicalTrials.gov" and "ClinicalTrials.gov online training" resources in the same web page.
3. Along with the request to add hyperlinks, reach out to the American Cancer Society and Oncology groups to ask that more information be included in the information packages typically given to cancer patients once they are diagnosed.
4. Write a paper to publish the results of this research study.
5. Develop a new website to stress the need to advance cancer patients' involvement in clinical trials, and to provide opportunity to access the "NCI phone and live online chat service", "ClinicalTrials.gov" and "ClinicalTrials.gov online training" web sources.

   Some of these recommendations are in progress or have been implemented soon after the study was completed. The website has been created with domain name "cancerclinicaltrialsinfo.com".

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# Appendix A

## Questionnaire
## Survey "Assessment of Public use of the FDA web site"

**1. Master Thesis-Appendix 1**

This questionnaire is intended to collect information for a research project. By completing the survey you are agreeing to participate in the research project.

It is completely confidential; there is no way to identify the subject with his or her answers.

Please be honest answering the questions.

It is designed to collect information from adult individuals that live in USA only, therefore if you are not at least 18 years old or do not live in USA or Puerto Rico, please exit the survey now. The option is at the top right corner.

**2.**

**1. Your age (choose a range only if you do not mind)**

- ◯ Less than 18 years old
- ◯ Older than 18 years
- ◯ 18-30 years
- ◯ 31-50 years
- ◯ 50-100 years

**3. Section I**

**1. Your gender**

- ◯ Male
- ◯ Female
- ◯ Skip This Question

**4. Section II**

**1. US location where you live**

| | | |
|---|---|---|
| ◯ Alabama | ◯ Kentucky | ◯ Ohio |
| ◯ Alaska | ◯ Louisiana | ◯ Oklahoma |
| ◯ American Samoa | ◯ Maine | ◯ Oregon |
| ◯ Arizona | ◯ Maryland | ◯ Pennsylvania |
| ◯ Arkansas | ◯ Massachusetts | ◯ Puerto Rico |
| ◯ California | ◯ Michigan | ◯ Rhode Island |
| ◯ Colorado | ◯ Minnesota | ◯ South Carolina |
| ◯ Connecticut | ◯ Mississippi | ◯ South Dakota |
| ◯ Delaware | ◯ Missouri | ◯ Tennessee |
| ◯ District of Columbia | ◯ Montana | ◯ Texas |
| ◯ Florida | ◯ Nebraska | ◯ Utah |
| ◯ Georgia | ◯ Nevada | ◯ Vermont |
| ◯ Guam | ◯ New Hampshire | ◯ Virginia |
| ◯ Hawaii | ◯ New Jersey | ◯ Virgin Islands |
| ◯ Idaho | ◯ New Mexico | ◯ Washington |
| ◯ Illinois | ◯ New York | ◯ West Virginia |
| ◯ Indiana | ◯ North Carolina | ◯ Wisconsin |
| ◯ Iowa | ◯ North Dakota | ◯ Wyoming |
| ◯ Kansas | ◯ Northern Marianas Islands | ◯ No USA resident |

**5.**

**1. Highest education level obtained**

◯ Less than High School

◯ High School

◯ College Degree

◯ Skip This Question

**6.**

**1. What is your current and primary occupation? If presently unemployed, what was your most recent occupation?**

- ◯ Accountant
- ◯ Administrative Assistant
- ◯ Architect
- ◯ Bookkeepers
- ◯ Businessperson/Executive
- ◯ Butcher
- ◯ Caretaker
- ◯ Cashiers
- ◯ Chef/Cook/Baker/Fast Food
- ◯ Cleaning Maintenance
- ◯ Computer-Any field
- ◯ Construction
- ◯ Customer service
- ◯ Driver Bus/Taxi/Truck
- ◯ Economist
- ◯ Electrician
- ◯ Engineer
- ◯ Farmer
- ◯ Fisherman
- ◯ Flight Attendant
- ◯ Garbageman
- ◯ Hairdresser
- ◯ Journalist
- ◯ Laborer
- ◯ Landscaping
- ◯ Law
- ◯ Mechanic
- ◯ Medical Assistant
- ◯ Miner
- ◯ Musician
- ◯ Nurse
- ◯ Painter
- ◯ Photographer
- ◯ Physician
- ◯ Physician-Infectious Disease
- ◯ Physician-Oncology
- ◯ Pilot
- ◯ Plumber
- ◯ Police Officer
- ◯ Politician
- ◯ Prison Officer/Warder
- ◯ Receptionist
- ◯ Retail Salesperson
- ◯ Sales Representative
- ◯ Scientist-Any field
- ◯ Staying at Home Parent
- ◯ Soldier
- ◯ Student
- ◯ Teacher/Professor
- ◯ TV/Movies-Any field
- ◯ Waiter/Waitresses
- ◯ Writer
- ◯ Other

**7.**

**1. Do you keep yourself up to date with information about clinical trials?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

**8.**

**1. Do you discuss with your patients to take into consideration clinical trials as a treatment option?**

- ◯ Always discuss clinical trials treatment options
- ◯ Only for trials of innovative/modern medicine
- ◯ Never, if there is an approved therapy to treat the patient's condition
- ◯ Skip This Question

## 9.

**1. Are you a cancer patient,**
**cancer survivor**
**or the closest one to a cancer patient?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

## 10. Section III

**1. Name the disease**

- ◯ Bladder Cancer
- ◯ Brain Cancer
- ◯ Breast Cancer
- ◯ Colon/Rectal Cancer
- ◯ Endometrial Cancer
- ◯ Kidney Cancer
- ◯ Leukemia
- ◯ Lung Cancer
- ◯ Melanoma
- ◯ Non-Hodgkin Lymphoma
- ◯ Ovarian Cancer
- ◯ Pancreatic Cancer
- ◯ Prostate Cancer
- ◯ Thyroid Cancer
- ◯ Other
- ◯ Skip This Question

**11.**

**1. Did your Physician inform you about experimental drugs or clinical trials that are treatment options for your type of cancer?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

**12.**

**1. Did you conduct your own research with regard to your disease?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

**13.**

**1. Did you search for clinical trials as a treatment option for your disease?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

## 14.

**1. Which site you search information about cancer?**

- ☐ American Cancer Society
- ☐ Cancer Centers or Cancer Institutes such University Hospitals
- ☐ Cancer Information World
- ☐ FDA website (Food and Drug Administration)
- ☐ Just Search by the Name of the Disease
- ☐ Medicine Net
- ☐ National Cancer Institute (NCI)
- ☐ The American Association for Cancer Research (AACR)
- ☐ Web MD
- ☐ Wikipidia
- ☐ Others
- ☐ Skip This Question

Which others

## 15.

**1. Do you know what the IT-101 or CRLX101 is in relation to cancer- solid tumors?**

- ◯ Yes, My Doctor explained it
- ◯ Yes, I found out that information
- ◯ No
- ◯ Skip This Question

## 16.

**1. Do you know what the "I SPY Trial" is?**

- ◯ Yes, My Doctor explained it
- ◯ Yes, I found out that information
- ◯ No
- ◯ Skip This Question

## 17. Section IV

**1. Do you know what the FDA (Food and Drug Administration) is?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

## 18.

**1. Do you think the FDA is doing their job to protect and support the health of the general public?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

## 19.

**1. Do you trust the FDA approval decisions over the products they regulate such as drugs, medical devices and biological products?**

- ◯ Yes
- ◯ No
- ◯ Skip this Question

## 20.

**1. Do you search the FDA website?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

## 21.

**1. Does the FDA website provide information about CANCER clinical trials?**

- ◯ Yes
- ◯ No
- ◯ I do not know
- ◯ Skip This Question

**22.**

**1. Is clinical trials information in FDA website easily accesible?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

**23.**

**1. How many cancer and neoplasms studies are listed in the FDA website?**

- ◯ >350
- ◯ None
- ◯ I do not know
- ◯ Skip This Question

**24.**

**1. Do you know what biological markers (biomarkers) are?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

**25.**

**1. Do you know how biomarkers are being use in modern medical treatments?**

- ◯ Yes
- ◯ No
- ◯ Skip This Question

**26.**

**1. How did you learn about biomarkers?**

- ◯ My Doctor explained what biomarkers are
- ◯ Through my own search of information
- ◯ Skip This Question

## 27.

**1. Would you be willing to participate in a clinical trial if you learn that the trial is a treatment option (you will receive the approved stantand treatment)?**

- ◯ Yes
- ◯ No
- ◯ Maybe, I would need more information
- ◯ Skip This Question

## 28. Additional Comments

**1. Optional**

**Any additional comments (Such as therapy or experience with the disease. Do not provide your name or identity, completely anonymous.)**

## 29. Inclusion criteria

You do not meet the inclusion criteria to participate in the study.

## 30. THANK YOU

I really appreciate your participation.

Please use your social networks to refer the survey link to other people who could potentially participate in the study.

# Appendix B

## Survey "Assessment of Public use of the FDA web site"

## Results Summary

| | |
|---|---|
| **Total Started Survey:** | **337** |
| **Total Completed Survey:** | **309 (91.7%)** |

## Appendix 1

SurveyMonkey

**1. Your age (choose a range only if you do not mind) [Cual es tu edad]**

| | Response Percent | Response Count |
|---|---|---|
| Less than 18 years old | 0.3% | 1 |
| Older than 18 years | 0.9% | 3 |
| 18-30 years | 6.8% | 23 |
| **31-50 years** | **63.8%** | **215** |
| 50-100 years | 28.2% | 95 |
| | **answered question** | **337** |
| | **skipped question** | **0** |

**2. Your gender**

| | Response Percent | Response Count |
|---|---|---|
| Male [masculino] | 39.8% | 132 |
| **Female [femenino]** | **59.6%** | **198** |
| Skip This Question | 0.6% | 2 |
| | **answered question** | **332** |
| | **skipped question** | **5** |

**3. US location where you live [Donde vives]**

| | Response Percent | Response Count |
|---|---|---|
| Alabama | 2.4% | 8 |
| Alaska | 0.0% | 0 |
| American Samoa | 0.0% | 0 |
| Arizona | 0.6% | 2 |
| Arkansas | 0.9% | 3 |
| California | 0.9% | 3 |
| Colorado | 0.0% | 0 |
| Connecticut | 0.6% | 2 |
| Delaware | 0.0% | 0 |
| District of Columbia | 0.0% | 0 |
| Florida | 7.9% | 26 |
| **Georgia** | **43.0%** | **141** |
| Guam | 0.0% | 0 |
| Hawaii | 0.0% | 0 |
| Idaho | 0.0% | 0 |
| Illinois | 0.6% | 2 |
| Indiana | 0.6% | 2 |
| Iowa | 0.0% | 0 |
| Kansas | 0.0% | 0 |
| Kentucky | 0.0% | 0 |
| Louisiana | 0.0% | 0 |
| Maine | 0.0% | 0 |
| Maryland | 0.6% | 2 |

| | | |
|---|---|---|
| Massachusetts | 0.3% | 1 |
| Michigan | 0.0% | 0 |
| Minnesota | 0.0% | 0 |
| Mississippi | 0.0% | 0 |
| Missouri | 0.3% | 1 |
| Montana | 0.3% | 1 |
| Nebraska | 0.0% | 0 |
| Nevada | 0.0% | 0 |
| New Hampshire | 0.0% | 0 |
| New Jersey | 0.6% | 2 |
| New Mexico | 0.0% | 0 |
| New York | 2.1% | 7 |
| North Carolina | 0.9% | 3 |
| North Dakota | 0.0% | 0 |
| Northern Marianas Islands | 0.0% | 0 |
| Ohio | 0.3% | 1 |
| Oklahoma | 0.3% | 1 |
| Oregon | 0.0% | 0 |
| Pennsylvania | 1.8% | 6 |
| Puerto Rico | 29.3% | 96 |
| Rhode Island | 0.0% | 0 |
| South Carolina | 0.9% | 3 |
| South Dakota | 0.0% | 0 |
| Tennessee | 0.0% | 0 |
| Texas | 2.1% | 7 |
| Utah | 0.0% | 0 |

| | | |
|---|---|---|
| Vermont | 0.0% | 0 |
| Virginia | 1.5% | 5 |
| Virgin Islands | 0.0% | 0 |
| Washington | 0.0% | 0 |
| West Virginia | 0.0% | 0 |
| Wisconsin | 0.6% | 2 |
| Wyoming | 0.0% | 0 |
| No USA resident | 0.3% | 1 |
| | answered question | 328 |
| | skipped question | 9 |

**4. Highest education level obtained [Mayor grado de educacion alcanzada]**

| | Response Percent | Response Count |
|---|---|---|
| Less than High School [no complete grado 12] | 1.8% | 6 |
| High School [Hasta grado 12] | 13.8% | 45 |
| **College Degree [Un grado de universidad]** | **84.0%** | **274** |
| Skip This Question | 0.3% | 1 |
| | answered question | 326 |
| | skipped question | 11 |

**5. What is your current and primary occupation? If presently unemployed, what was your most recent occupation? [En que trabajas?, Si estas desempleado en que trabajabas?]**

| | Response Percent | Response Count |
|---|---|---|
| Accountant [Contabilidad] | 1.5% | 5 |
| Administrative Assistant [Secretarial] | 4.6% | 15 |
| Architect [Arquitectura] | 0.3% | 1 |
| Bookkeepers [Mantiene los libros de cuentas] | 0.3% | 1 |
| Businessperson/Executive [Negocio propio] | 4.9% | 16 |
| Butcher [Carnicero] | 0.0% | 0 |
| Caregiver [Cuida enfermos o ninos] | 0.9% | 3 |
| Cashiers [Cajero/a] | 0.6% | 2 |
| Chef/Cook/Baker/Fast Food [Cocinero/ preparador de comida rapida] | 0.6% | 2 |
| Cleaning Maintenance [Limpieza] | 0.3% | 1 |
| Computer-Any field [Cualquier campo en Computadoras] | 3.7% | 12 |
| Construction [Construccion] | 0.9% | 3 |
| Customer service [Servicio al cliente] | 2.1% | 7 |
| Driver Bus/Taxi/Truck [Chofer] | 0.3% | 1 |
| Economist | 0.6% | 2 |
| Electrician | 0.3% | 1 |
| Engineer [Ingeniero] | 3.4% | 11 |
| Farmer [Agricultor] | 0.0% | 0 |
| Fisherman [Pescador] | 0.0% | 0 |

| | | | |
|---|---|---|---|
| Flight Attendant [Asistente de Vuelos] | | 0.0% | 0 |
| Garbageman [Collector de basura] | | 0.0% | 0 |
| Hairdresser [Estilista] | | 0.9% | 3 |
| Journalist [Reportero/a] | | 0.0% | 0 |
| Laborer [Empleado de produccion] | | 0.6% | 2 |
| Landscaping [Jardinero/a] | | 0.0% | 0 |
| Law [Leyes] | | 0.6% | 2 |
| Mechanic [Mecanico] | | 0.3% | 1 |
| Medical Assistant [Asistente medico] | | 0.6% | 2 |
| Miner [Minero] | | 0.0% | 0 |
| Musician [Musico] | | 0.3% | 1 |
| Nurse [Enfermeria] | | 1.2% | 4 |
| Painter [Pintor] | | 0.0% | 0 |
| Photographer [Fotografo] | | 0.3% | 1 |
| Physical Therapy [Terapista fisico] | | 0.9% | 3 |
| Physician [Doctor] | | 3.4% | 11 |
| Physician-Infectious Disease [Doctor de Enfermedades Infecciosas] | | 0.3% | 1 |
| Physician-Oncology [Doctor de Oncologia] | | 0.0% | 0 |
| Pilot [Piloto] | | 0.0% | 0 |
| Plumber [Plomero] | | 0.0% | 0 |
| Police Officer [Policia] | | 0.3% | 1 |
| Politician | | 0.0% | 0 |
| Prison Officer/Warder [Guardia o Jefe de la Prision] | | 0.0% | 0 |

| | | |
|---|---|---|
| Receptionist [Recepcionista] | 0.9% | 3 |
| Retail Salesperson [Vendedor] | 0.9% | 3 |
| Sales Representative [Representante de ventas] | 2.8% | 9 |
| Scientist-Any field | 18.7% | 61 |
| Staying at Home Parent [Padre/madre en la casa para cuidar los hijos] | 1.5% | 5 |
| Soldier [Soldado] | 0.6% | 2 |
| Student [Estudiante] | 1.8% | 6 |
| Teacher/Professor [Maestro/a de escuela o universidad] | 9.2% | 30 |
| TV/Movies-Any field | 0.0% | 0 |
| Waiter/Waitresses [Mesero/a] | 0.3% | 1 |
| Writer [Escritor/a] | 0.3% | 1 |
| **Other** | **27.6%** | **90** |
| | **answered question** | **326** |
| | **skipped question** | **11** |

**6. Do you keep yourself up to date with information about clinical trials? [Te mantienes al dia informado sobre estudios clinicos?]**

| | Response Percent | Response Count |
|---|---|---|
| **Yes** | **62.5%** | **10** |
| No | 37.5% | 6 |
| Skip This Question | 0.0% | 0 |
| | **answered question** | **16** |
| | **skipped question** | **321** |

**7. Do you discuss with your patients to take into consideration clinical trials as a treatment option? [Discute la participacion en estudios clinicos como una option de tratamiento para el paciente?]**

| | Response Percent | Response Count |
|---|---|---|
| Always discuss clinical trials treatment options [Siempre le presento los estudios clinicos como una option para tratarlos] | 27.3% | 3 |
| Only for trials of innovative/modern medicine [Les presento estudios clinicos para tratamientos que son modernos y innovativos] | 27.3% | 3 |
| Never, if there is an approved therapy to treat the patient's condition [Nunca si hay tratamientos aprovados] | 27.3% | 3 |
| Skip This Question | 18.2% | 2 |
| | answered question | 11 |
| | skipped question | 326 |

**8. Are you a cancer patient, cancer survivor or the closest one to a cancer patient? [Eres un paciente de cancer, sobreviviente de cancer o la persona que cuida o cuido el paciente de cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 24.9% | 81 |
| No | 74.2% | 241 |
| Skip This Question | 0.9% | 3 |
| | answered question | 325 |
| | skipped question | 12 |

**9. Name the disease [Que tipo de cancer]**

| | Response Percent | Response Count |
|---|---|---|
| Bladder Cancer [Vejiga] | 2.4% | 2 |
| Brain Cancer [Cerebro] | 6.0% | 5 |
| **Breast Cancer [Del seno]** | **15.5%** | **13** |
| Colon/Rectal Cancer [Colon o anal] | 10.7% | 9 |
| Endometrial Cancer [Endometrio] | 0.0% | 0 |
| Kidney Cancer [Rinones] | 1.2% | 1 |
| Leukemia [sangre] | 4.8% | 4 |
| Lung Cancer [Pulmon] | 11.9% | 10 |
| Melanoma | 6.0% | 5 |
| Non-Hodgkin Lymphoma | 6.0% | 5 |
| Ovarian Cancer | 6.0% | 5 |
| Pancreatic Cancer | 3.6% | 3 |
| Prostate Cancer | 11.9% | 10 |
| Thyroid Cancer | 2.4% | 2 |
| Other | 10.7% | 9 |
| Skip This Question | 1.2% | 1 |
| | **answered question** | **84** |
| | **skipped question** | **253** |

**10. Did your Physician inform you about experimental drugs or clinical trials that are treatment options for your type of cancer? [Discutio tu medico sobre algun estudio clinico que podia ser una option de tratamiento para tu tipo de cancer]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 33.8% | 27 |
| No | 52.5% | 42 |
| Skip This Question | 13.8% | 11 |
| answered question | | 80 |
| skipped question | | 257 |

**11. Did you conduct your own research with regard to your disease? [Buscaste information sobre tu tipo de cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 59.0% | 46 |
| No | 30.8% | 24 |
| Skip This Question | 10.3% | 8 |
| answered question | | 78 |
| skipped question | | 259 |

**12. Did you search for clinical trials as a treatment option for your disease? [Buscaste information sobre estudios clinicos para tu tipo de cancer?]**

| | | Response Percent | Response Count |
|---|---|---|---|
| Yes |  | 37.8% | 17 |
| No |  | 60.0% | 27 |
| Skip This Question |  | 2.2% | 1 |
| | | answered question | 45 |
| | | skipped question | 292 |

**13. Which site you search information about cancer? [Donde buscate informacion sobre cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| **American Cancer Society** | **60.9%** | **28** |
| Cancer Centers or Cancer Institutes such University Hospitals | 26.1% | 12 |
| Cancer Information World | 8.7% | 4 |
| FDA website (Food and Drug Administration) | 13.0% | 6 |
| Just Search by the Name of the Disease [Busque por el nombre del cancer] | 50.0% | 23 |
| Medicine Net | 6.5% | 3 |
| National Cancer Institute (NCI) | 17.4% | 8 |
| The American Association for Cancer Research (AACR) | 8.7% | 4 |
| Web MD | 28.3% | 13 |
| Wikipidia | 15.2% | 7 |
| Others [Otra fuente de informacion] | 17.4% | 8 |
| Skip This Question | 2.2% | 1 |
| | Which others [Cuales otros] | 3 |
| | **answered question** | **46** |
| | **skipped question** | **291** |

**14. Do you know what the IT-101 or CRLX101 is in relation to cancer- solid tumors? [Sabes que es IT-101 o CRLX101 para tumores cancerosos?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes, My Doctor explained it [Si, me explico mi doctor] | 1.3% | 1 |
| Yes, I found out that information [Si, encontre esa informacion] | 1.3% | 1 |
| **No** | **89.7%** | **70** |
| Skip This Question | 7.7% | 6 |
| | **answered question** | **78** |
| | **skipped question** | **259** |

**15. Do you know what the "I SPY Trial" is? [Sabes lo que es el estudio I SPY Trial?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes, My Doctor explained it [Si, mi doctor me explico] | 3.9% | 3 |
| Yes, I found out that information [Si, encontre esa informacion] | 3.9% | 3 |
| **No** | **90.8%** | **69** |
| Skip This Question | 1.3% | 1 |
| | **answered question** | **76** |
| | **skipped question** | **261** |

**16. Do you know what the FDA (Food and Drug Administration) is? [Sabes que es el FDA (La administracion de alimentos y drogas)?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 96.6% | 309 |
| No | 3.4% | 11 |
| Skip This Question | 0.0% | 0 |
| answered question | | 320 |
| skipped question | | 17 |

**17. Do you think the FDA is doing their job to protect and support the health of the general public? [Crees que el FDA esta haciendo el trabajo que debe de proteger y mantener la salud de los consumidores?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 69.6% | 215 |
| No | 25.6% | 79 |
| Skip This Question | 4.9% | 15 |
| answered question | | 309 |
| skipped question | | 28 |

**18. Do you trust the FDA approval decisions over the products they regulate such as drugs, medical devices and biological products? [Confias en las decisiones que FDA toma para apruebar los productos que regulan?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 67.2% | 207 |
| No | 28.6% | 88 |
| Skip this Question | 4.2% | 13 |
| answered question | | 308 |
| skipped question | | 29 |

**19. Do you search the FDA website? [Visitas el website de FDA?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 30.6% | 94 |
| No | 67.8% | 208 |
| Skip This Question | 1.6% | 5 |
| answered question | | 307 |
| skipped question | | 30 |

**20. Does the FDA website provide information about CANCER clinical trials? [Y el website de FDA tiene informacion sobre estudios clinicos para cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 10.4% | 32 |
| No | 3.6% | 11 |
| I do not know [No se] | 82.1% | 252 |
| Skip This Question | 3.9% | 12 |
| answered question | | 307 |
| skipped question | | 30 |

**21. Is clinical trials information in FDA website easily accesible? [Es facil de encontrar esa informacion de estudios clinicos en el website de FDA?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 78.1% | 25 |
| No | 18.8% | 6 |
| Skip This Question | 3.1% | 1 |
| answered question | | 32 |
| skipped question | | 305 |

**22. How many cancer and neoplasms studies are listed in the FDA website? [Para cuantas condiciones de cancer hay estudios clinicos en el website de FDA?]**

| | Response Percent | Response Count |
|---|---|---|
| More than 350 [Mas de 350] | 6.3% | 2 |
| None [Ninguno] | 3.1% | 1 |
| I do not know [No se] | 78.1% | 25 |
| Skip This Question | 12.5% | 4 |
| answered question | | 32 |
| skipped question | | 305 |

**23. Do you know what biological markers (biomarkers) are? [Sabes lo que son marcadores biologicos?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 47.6% | 151 |
| No | 50.2% | 159 |
| Skip This Question | 2.2% | 7 |
| answered question | | 317 |
| skipped question | | 20 |

**24. Do you know how biomarkers are being use in modern medical treatments? [Sabes para que se estan usando los marcadores biologicos en tratamientos modernos?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 62.5% | 95 |
| No | 36.8% | 56 |
| Skip This Question | 0.7% | 1 |
| answered question | | 152 |
| skipped question | | 185 |

**25. How did you learn about biomarkers? [Como te enteraste de lo que son los marcadores biologicos?]**

| | Response Percent | Response Count |
|---|---|---|
| My Doctor explained what biomarkers are [Mi doctor me explico] | 4.6% | 7 |
| **Through my own search of information [Autoeducandome]** | **86.8%** | **131** |
| Skip This Question | 8.6% | 13 |
| | **answered question** | **151** |
| | **skipped question** | **186** |

**26. Would you be willing to participate in a clinical trial if you learn that the trial is a treatment option (you will receive the approved stantand treatment)? [Estaria dispuesto a participar en estudios clinicos como una opcion de tu tratamiento?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 15.6% | 49 |
| No | 26.4% | 83 |
| **Maybe, I would need more information [Quizas, necesito mas informacion]** | **55.4%** | **174** |
| Skip This Question | 2.5% | 8 |
| | **answered question** | **314** |
| | **skipped question** | **23** |

| 27. Optional Any additional comments (Such as therapy or experience with the disease. Do not provide your name or identity, completely anonymous.) [Opcional-Cualquier comentario que quieras compartir. El tratamiento para cancer recibido, experiencias durante la enfermedad. No incluya nombre o identidad.] | |
|---|---|
| | Response Count |
| | 36 |
| answered question | 36 |
| skipped question | 301 |

**Page 28, Q1. Optional**
**Any additional comments (Such as therapy or experience with the disease. Do not provide your name or identity, completely anonymous.)**

**[Opcional-Cualquier comentario que quieras compartir. El tratamiento para cancer recibido, experiencias durante la enfermedad. No incluya nombre o ide...**

| | | |
|---|---|---|
| 1 | I have my brother with skin, and colon cancer in jail, where i know that he won't received the best care for his condition. My mother in law is a cancer survival. Thanks | Oct 30, 2010 3:48 AM |
| 2 | none | Oct 30, 2010 5:23 AM |
| 3 | My experience as a friend of few cancer victims/cancer survivors is that the medicine field is extremely politicized, and in many cases, because of this, many are falsely diagnosed or diagnosed to late where so little can be done. | Oct 30, 2010 12:29 PM |
| 4 | NO COMMENTS AT ALL. | Oct 30, 2010 5:27 PM |
| 5 | none | Nov 1, 2010 8:17 AM |
| 6 | N/A | Nov 1, 2010 10:30 AM |
| 7 | I have not developed any cancer affliction so far. Although now I devote my life to music, I earned a PhD in chemistry and worked in the Regulatory Affairs field in the Pharmaceutical Industry and am very aware of the role of the FDA. Sadly, I have lost friends to cancer. More needs to be done. | Nov 2, 2010 6:20 PM |
| 8 | None | Nov 4, 2010 12:09 PM |
| 9 | I didn't have cancer, but all my mother family had suffered cancer. My grandma (ovarian cancer), my grandpa (throat cancer); my grandma sister (leukemia), etc. | Nov 10, 2010 4:28 PM |
| 10 | I had surgery for colon cancer in 1991. About 1 foot of colon was removed. The malignant tumor was slow-growing and about 4.5 cm. in diameter. Nine or 10 nearby lympth nodes were also removed. I have been free of cancer since the operation. Chemotherapy treatment was used after the surgery. | Nov 11, 2010 9:14 PM |
| 11 | POR EL MOMENTO NO HE PASADO POR ESA EXPERIENCIA | Nov 14, 2010 1:47 PM |
| 12 | Si tuviera la necesidad estaria ha ser parte de un estudio si de esta manera puede adelantar la investigacion contra la lucha para esta enfermedad | Nov 17, 2010 5:13 AM |
| 13 | I'm Good | Nov 17, 2010 12:43 PM |
| 14 | MANY OF MY FRIENDS HAVE BEEN DIAGNOSED WITH CANCER AND SOME HAVE DIED. I SURE WOULD LIKE TO KNOW THE FDA WAS DOING ALL IT COULD DO TO COME UP WITH A CURE. | Nov 18, 2010 7:57 AM |
| 15 | Cuide a mi hermana que fallecio de cancer de pancreas y ella se sometio a medicamentos de quimoterapia realmente no se si fueron medicamentos experimentales pero para mi Ella fallecio por concecuencias del medicamento y no por Los efectos del cancer. | Nov 19, 2010 5:59 PM |

**Page 28, Q1. Optional**
**Any additional comments (Such as therapy or experience with the disease. Do not provide your name or identity, completely anonymous.)**

**[Opcional-Cualquier comentario que quieras compartir. El tratamiento para cancer recibido, experiencias durante la enfermedad. No incluya nombre o ide...**

| | | |
|---|---|---|
| 16 | La FDA tiene una responsabilidad muy grande en aprobar drogas y alimentos seguros para el beneficios de la población, pero entiendo que hay mucha información que se transmite muy lenta a la población. (Recibi un e-mail hace poco sobre un tratamiento para el cancer casero, su receta era Moler una penca de Sábila sin pelar y miel pura y un poco de brandi - para que actuara como vaso dilatador) es efectivo, no lo se. Tambien se dice que el plastico al calentar comida en los microhondas sueltan unas sustancias que son cancerosas y la FDA no se a expresado sobre estos temas o por lo menos no tengo conocimiento que lo hayan hecho. Pienso que la FDA debe de tomar un rol mas activo. | Nov 21, 2010 5:00 PM |
| 17 | I am thankful for those who do participate in human clinical trials, but I would not be one of them unless I had an incurable disease and was desperate to try anything. | Nov 29, 2010 11:10 AM |
| 18 | I was immediately referred to an oncology surgeon and followed his advice/directions. Thankfully all of my cancer was removed and it had not spread to my lymph nodes as was suspected. | Dec 1, 2010 9:49 AM |
| 19 | You need to edit the questions better. I saw a grammatical error. | Dec 1, 2010 10:28 AM |
| 20 | The Simon Cancer Center at the IU MedCenter in Indianapolis is the BEST. | Dec 1, 2010 7:10 PM |
| 21 | Thank you.... wonderful job.....! | Dec 2, 2010 7:26 AM |
| 22 | The bipolar nature of the questions on this survey may skew your results - forcing people to chose Y/N may decrease your variability and you might miss some nuances in responses. | Dec 3, 2010 9:00 AM |
| 23 | Es importante senalar que quien tuvo Cancer fue mi mama, y murio de esa condicion. | Dec 16, 2010 5:40 AM |
| 24 | I helped nurse a close relative with cancer. | Dec 16, 2010 5:48 AM |
| 25 | Vitamina C intravenosa a altas dosificaciones en conbinación con la Vit B12 y complejo B se han estado utilizando en medicina preventiva con mucho exito en sus pacientes. Cambios en la alimentación como la eliminación de carmes rojas (Res) negras (cerdo) y el pollo el cual tiene muchas hormonas. Evitar el Consumo de comidas enlatadas y gluten, entre muchas otras tecnicas. | Dec 16, 2010 7:24 AM |
| 26 | La ciudadania necesita mas informacion y orientacion sobre dietas, estilos de vida, que lleven a la poblacion a minimizar los riesgos de desarrollar cancer. | Dec 22, 2010 8:03 AM |

**Page 28, Q1. Optional**
**Any additional comments (Such as therapy or experience with the disease. Do not provide your name or identity, completely anonymous.)**

**[Opcional-Cualquier comentario que quieras compartir. El tratamiento para cancer recibido, experiencias durante la enfermedad. No incluya nombre o ide...**

| | | |
|---|---|---|
| 27 | hay mucho hermetismo de tratamientos nuevos, no quieren decir donde, ni cuando uno preguntar, solo un pequeño grupo se beneficia, como es el caso de familiares de doctores, o allegados, o personas que tienen algún contacto con la política el cual la información fluye rápido y consiguen ayudas para su enfermedad, y mas aun ,se benefician de medicamentos, aunque sea placebos, pero, la atención medica es privilegiada de un grupo, muy reducido, es el caso de un paciente de cáncer el cual tuvo que hacer colectas para su viaje a estados unidos, pero un conocido , de esta persona, con solvencia económica muy estable, consiguió ayuda medica de un research y le dieron transportación aérea, acomodo, sin embargo quien lo necesitaba, pidió ayuda económica en la comunidad y tenia que buscar su sustento, quien lo necesita, no es ayudado, los médicos saben de toda ayuda medica, y trabajos investigativos que ofrecen todo tipo de ayuda , medicamentos, alojo, y mas aun dispensa económica, no se le hace saber a personas que desean ayudar a la ciencia, pero tampoco los médicos son comunicativos o abiertos a ayudar a sus pacientes. escondiendo toda información si no recibe una regalía económica o mas bien un por ciento económico de referido, por ende es importante crear en los nuevos médicos en las escuelas de medicinas el concepto humanismo, y mas aun, no ver todo cuanto dinero me toca si te ayudo en tu trabajo investigativo, por ende y finalizar, hay que buscar gente de que deseen ser ayudados y por su ayuda a la ciencia se le brinde ayuda, en pos los que desean ayudar a otros, buscar médicos que deseen adelantar la ciencia, no atrasarla por sus beneficios económicos o mas bien el yate, la casa el auto deportivo, que es lo que le gusta el medico que tiene esa información y esconde todo solo para un grupo. | Dec 26, 2010 10:26 AM |
| 28 | no comment | Jan 13, 2011 9:24 AM |
| 29 | Sería bueno que el FDA tuviera un link donde uno se pudiera logear y poder recibir información sobre estudios, adelantos científicos sobre enfermedades en específico. | Jan 14, 2011 7:07 PM |
| 30 | I really thing that the cure for cancer had been discover, but something is hiring. | Jan 18, 2011 5:17 PM |
| 31 | I'm Psychotherapist and I haven't work with this type of patients but I will love to work with them. Thanks!!! | Jan 31, 2011 8:15 PM |
| 32 | When you are diagnosed with cancer even if you are a doctor you may not want to know the alternatives of treatment depending if you are in denial or depresed. | Feb 10, 2011 7:34 PM |
| 33 | Experienced cancer with one of my parent years ago. The treatment given was low radiation for 6 weeks after diagnosis. A more aggressive approach, example surgery, was not recommended by the doctor as the parent was advanced in age. The radiation treatment did not have any effect on the cancer. It sapped my parent energy and quality of life. Eventually excruciating pain was experienced and morphine had to be administered. Death occurred after 9 months of the first diagnosis. | Feb 19, 2011 10:44 PM |
| 34 | I tried to research clinical trials for my mother, who had lung cancer, & did not have much luck. A friend is now in a clinical trial for prostate cancer, as a last resort. It's giving him more time with a good quality of life & hoipefully will help others in the future. | Feb 28, 2011 7:11 PM |

**Page 28, Q1. Optional**
**Any additional comments (Such as therapy or experience with the disease. Do not provide your name or identity, completely anonymous.)**

**[Opcional-Cualquier comentario que quieras compartir. El tratamiento para cancer recibido, experiencias durante la enfermedad. No incluya nombre o ide...**

| | | |
|---|---|---|
| 35 | None | Mar 1, 2011 12:00 PM |
| 36 | N/A | Mar 2, 2011 7:36 AM |

# Appendix C

Chi-Square for Cancer Patients by Gender

-Tendency to Search Cancer Information

- Tendency to Search Cancer Clinical Trials Information

**Active Filter:** Gender + Cancer Patient + Search FDA

**Filtered:** Female 55

Male 26

**Filtered:** 61

## Appendix 1

SurveyMonkey

### 1. Your gender

| | Response Percent | Response Count |
|---|---|---|
| Male [masculino] | 0.0% | 0 |
| Female [femenino] | 100.0% | 55 |
| Skip This Question | 0.0% | 0 |
| answered question | | 55 |
| skipped question | | 0 |

### 2. Are you a cancer patient, cancer survivor or the closest one to a cancer patient? [Eres un paciente de cancer, sobreviviente de cancer o la persona que cuida o cuido el paciente de cancer?]

| | Response Percent | Response Count |
|---|---|---|
| Yes | 100.0% | 55 |
| No | 0.0% | 0 |
| Skip This Question | 0.0% | 0 |
| answered question | | 55 |
| skipped question | | 0 |

**3. Did you conduct your own research with regard to your disease? [Buscaste information sobre tu tipo de cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 53.8% | 28 |
| No | 32.7% | 17 |
| Skip This Question | 13.5% | 7 |
| answered question | | 52 |
| skipped question | | 3 |

**4. Did you search for clinical trials as a treatment option for your disease? [Buscaste information sobre estudios clinicos para tu tipo de cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 25.9% | 7 |
| No | 70.4% | 19 |
| Skip This Question | 3.7% | 1 |
| answered question | | 27 |
| skipped question | | 28 |

## Appendix 1

SurveyMonkey

### 1. Your gender

| | Response Percent | Response Count |
|---|---|---|
| Male [masculino] | 100.0% | 26 |
| Female [femenino] | 0.0% | 0 |
| Skip This Question | 0.0% | 0 |
| answered question | | 26 |
| skipped question | | 0 |

### 2. Are you a cancer patient, cancer survivor or the closest one to a cancer patient? [Eres un paciente de cancer, sobreviviente de cancer o la persona que cuida o cuido el paciente de cancer?]

| | Response Percent | Response Count |
|---|---|---|
| Yes | 100.0% | 26 |
| No | 0.0% | 0 |
| Skip This Question | 0.0% | 0 |
| answered question | | 26 |
| skipped question | | 0 |

**3. Did you conduct your own research with regard to your disease? [Buscaste information sobre tu tipo de cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 69.2% | 18 |
| No | 26.9% | 7 |
| Skip This Question | 3.8% | 1 |
| answered question | | 26 |
| skipped question | | 0 |

**4. Did you search for clinical trials as a treatment option for your disease? [Buscaste information sobre estudios clinicos para tu tipo de cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 55.6% | 10 |
| No | 44.4% | 8 |
| Skip This Question | 0.0% | 0 |
| answered question | | 18 |
| skipped question | | 8 |

Chi-square Comparison for willingness of Cancer Patients to Search for Cancer Information and Cancer Clinical Trials by Gender

**Tabulated statistics: Gender Search for Cancer Information**

Using frequencies in Frequency

Rows: Gender Search for Cancer Inform  Columns: Sample

| | Female | Male | All |
|---|---|---|---|
| No | 17 | 7 | 24 |
| | 37.78 | 28.00 | 34.29 |
| | 15.43 | 8.57 | 24.00 |
| Yes | 28 | 18 | 46 |
| | 62.22 | 72.00 | 65.71 |
| | 29.57 | 16.43 | 46.00 |
| All | 45 | 25 | 70 |
| | 100.00 | 100.00 | 100.00 |
| | 45.00 | 25.00 | 70.00 |

Cell Contents: Count
% of Column
Expected count

Pearson Chi-Square = 0.682, DF = 1, P-Value = 0.409
Likelihood Ratio Chi-Square = 0.693, DF = 1, P-Value = 0.405
Fisher's exact test: P-Value = 0.444390

**Tabulated statistics: Search for Clinical Trial as treatment**

Using frequencies in Frequency

Rows: Search for Clinical Trial as tr  Columns: Sample

| | Female | Male | All |
|---|---|---|---|
| No | 19 | 8 | 27 |
| | 73.08 | 44.44 | 61.36 |
| | 15.95 | 11.05 | 27.00 |
| Yes | 7 | 10 | 17 |
| | 26.92 | 55.56 | 38.64 |
| | 10.05 | 6.95 | 17.00 |
| All | 26 | 18 | 44 |
| | 100.00 | 100.00 | 100.00 |
| | 26.00 | 18.00 | 44.00 |

Cell Contents: Count
% of Column
Expected count

Pearson Chi-Square = 3.678, DF = 1, P-Value = 0.055
Likelihood Ratio Chi-Square = 3.684, DF = 1, P-Value = 0.055
Fisher's exact test: P-Value = 0.0679385

Appendix D

Physicians Filtered Responses

And

Chi-Square Calculations For

-Tendency to search the FDA's website

-Awareness that the FDA's website list cancer clinical trials

**Active Filter:** Physician

**Filtered:** 12

## Appendix 1

SurveyMonkey

**1. What is your current and primary occupation? If presently unemployed, what was your most recent occupation? [En que trabajas?, Si estas desempleado en que trabajabas?]**

| | Response Percent | Response Count |
|---|---|---|
| Accountant [Contabilidad] | 0.0% | 0 |
| Administrative Assistant [Secretarial] | 0.0% | 0 |
| Architect [Arquitectura] | 0.0% | 0 |
| Bookkeepers [Mantiene los libros de cuentas] | 0.0% | 0 |
| Businessperson/Executive [Negocio propio] | 0.0% | 0 |
| Butcher [Carnicero] | 0.0% | 0 |
| Caregiver [Cuida enfermos o ninos] | 0.0% | 0 |
| Cashiers [Cajero/a] | 0.0% | 0 |
| Chef/Cook/Baker/Fast Food [Cocinero/ preparador de comida rapida] | 0.0% | 0 |
| Cleaning Maintenance [Limpieza] | 0.0% | 0 |
| Computer-Any field [Cualquier campo en Computadoras] | 0.0% | 0 |
| Construction [Construccion] | 0.0% | 0 |
| Customer service [Servicio al cliente] | 0.0% | 0 |
| Driver Bus/Taxi/Truck [Chofer] | 0.0% | 0 |
| Economist | 0.0% | 0 |
| Electrician | 0.0% | 0 |
| Engineer [Ingeniero] | 0.0% | 0 |

| | | | |
|---|---|---|---|
| Farmer [Agricultor] | | 0.0% | 0 |
| Fisherman [Pescador] | | 0.0% | 0 |
| Flight Attendant [Asistente de Vuelos] | | 0.0% | 0 |
| Garbageman [Collector de basura] | | 0.0% | 0 |
| Hairdresser [Estilista] | | 0.0% | 0 |
| Journalist [Reportero/a] | | 0.0% | 0 |
| Laborer [Empleado de produccion] | | 0.0% | 0 |
| Landscaping [Jardinero/a] | | 0.0% | 0 |
| Law [Leyes] | | 0.0% | 0 |
| Mechanic [Mecanico] | | 0.0% | 0 |
| Medical Assistant [Asistente medico] | | 0.0% | 0 |
| Miner [Minero] | | 0.0% | 0 |
| Musician [Musico] | | 0.0% | 0 |
| Nurse [Enfermeria] | | 0.0% | 0 |
| Painter [Pintor] | | 0.0% | 0 |
| Photographer [Fotografo] | | 0.0% | 0 |
| Physical Therapy [Terapista fisico] | | 0.0% | 0 |
| **Physician [Doctor]** |  | **91.7%** | **11** |
| Physician-Infectious Disease [Doctor de Enfermedades Infecciosas] |  | 8.3% | 1 |
| Physician-Oncology [Doctor de Oncologia] | | 0.0% | 0 |
| Pilot [Piloto] | | 0.0% | 0 |
| Plumber [Plomero] | | 0.0% | 0 |
| Police Officer [Policia] | | 0.0% | 0 |

| | | |
|---|---|---|
| Politician | 0.0% | 0 |
| Prison Officer/Warder [Guardia o Jefe de la Prision] | 0.0% | 0 |
| Receptionist [Recepcionista] | 0.0% | 0 |
| Retail Salesperson [Vendedor] | 0.0% | 0 |
| Sales Representative [Representante de ventas] | 0.0% | 0 |
| Scientist-Any field | 0.0% | 0 |
| Staying at Home Parent [Padre/madre en la casa para cuidar los hijos] | 0.0% | 0 |
| Soldier [Soldado] | 0.0% | 0 |
| Student [Estudiante] | 0.0% | 0 |
| Teacher/Professor [Maestro/a de escuela o universidad] | 0.0% | 0 |
| TV/Movies-Any field | 0.0% | 0 |
| Waiter/Waitresses [Mesero/a] | 0.0% | 0 |
| Writer [Escritor/a] | 0.0% | 0 |
| Other | 0.0% | 0 |
| | **answered question** | **12** |
| | **skipped question** | **0** |

**2. Do you keep yourself up to date with information about clinical trials? [Te mantienes al dia informado sobre estudios clinicos?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 66.7% | 8 |
| No | 33.3% | 4 |
| Skip This Question | 0.0% | 0 |
| answered question | | 12 |
| skipped question | | 0 |

**3. Do you discuss with your patients to take into consideration clinical trials as a treatment option? [Discute la participacion en estudios clinicos como una option de tratamiento para el paciente?]**

| | Response Percent | Response Count |
|---|---|---|
| **Always discuss clinical trials treatment options [Siempre le presento los estudios clinicos como una option para tratarlos]** | **37.5%** | **3** |
| Only for trials of innovative/modern medicine [Les presento estudios clinicos para tratamientos que son modernos y innovativos] | 12.5% | 1 |
| Never, if there is an approved therapy to treat the patient's condition [Nunca si hay tratamientos aprovados] | 25.0% | 2 |
| Skip This Question | 25.0% | 2 |
| answered question | | 8 |
| skipped question | | 4 |

**4. Do you search the FDA website? [Visitas el website de FDA?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 25.0% | 3 |
| No | 66.7% | 8 |
| Skip This Question | 8.3% | 1 |
| answered question | | 12 |
| skipped question | | 0 |

**5. Does the FDA website provide information about CANCER clinical trials? [Y el website de FDA tiene informacion sobre estudios clinicos para cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 16.7% | 2 |
| No | 0.0% | 0 |
| I do not know [No se] | 66.7% | 8 |
| Skip This Question | 16.7% | 2 |
| answered question | | 12 |
| skipped question | | 0 |

Chi-Square 1- Effect of Physicians subset in "Search the FDA website"

```
Tabulated statistics: Search FDA website- Physician

Using frequencies in Frequency
Rows: Search FDA website   Columns: Sample

       Non-Physician      Physician      All

No               205              3          208
                70.45          27.27        68.87
               200.42           7.58       208.00

Yes               86              8          94
                29.55          72.73        31.13
                90.58           3.42        94.00

All              291             11          302
                100.00         100.00       100.00
                291.00          11.00       302.00

Cell Contents:      Count
                    % of Column
                    Expected count

Pearson Chi-Square = 9.216, DF = 1, P-Value = 0.002
Likelihood Ratio Chi-Square = 8.359, DF = 1, P-Value = 0.004
* NOTE * 1 cells with expected counts less than 5
Fisher's exact test: P-Value =  0.0047697
```

Chi-Square 2-Effect of Physicians subset in "Awareness of Clinical Trials listed in FDA's website"

```
Tabulated statistics: Awareness of Clinical Trials information
in FDA website- Physicians

Using frequencies in Frequency
Rows: Search FDA website   Columns: Sample

       Non-Physician      Physician      All

No               244              8          252
                89.05          80.00        88.73
               243.13           8.87       252.00

Yes               30              2          32
                10.95          20.00        11.27
                30.87           1.13        32.00

All              274             10          284
                100.00         100.00       100.00
                274.00          10.00       284.00

Cell Contents:      Count
                    % of Column
                    Expected count

Pearson Chi-Square = 0.791, DF = 1, P-Value = 0.374
Likelihood Ratio Chi-Square = 0.666, DF = 1, P-Value = 0.415
* NOTE * 1 cells with expected counts less than 5
Fisher's exact test: P-Value =  0.313291
```

Appendix E

Cancer Patients Filtered Responses

And

Chi-Square Calculations For

-Tendency to search the FDA's website

-Awareness that the FDA's website list cancer clinical trials

## Appendix 1

SurveyMonkey

**1. Are you a cancer patient, cancer survivor or the closest one to a cancer patient? [Eres un paciente de cancer, sobreviviente de cancer o la persona que cuida o cuido el paciente de cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 24.9% | 81 |
| No | 74.2% | 241 |
| Skip This Question | 0.9% | 3 |
| answered question | | 325 |
| skipped question | | 12 |

## 2. Name the disease [Que tipo de cancer]

| | Response Percent | Response Count |
|---|---|---|
| Bladder Cancer [Vejiga] | 2.4% | 2 |
| Brain Cancer [Cerebro] | 6.0% | 5 |
| **Breast Cancer [Del seno]** | **15.5%** | **13** |
| Colon/Rectal Cancer [Colon o anal] | 10.7% | 9 |
| Endometrial Cancer [Endometrio] | 0.0% | 0 |
| Kidney Cancer [Rinones] | 1.2% | 1 |
| Leukemia [sangre] | 4.8% | 4 |
| Lung Cancer [Pulmon] | 11.9% | 10 |
| Melanoma | 6.0% | 5 |
| Non-Hodgkin Lymphoma | 6.0% | 5 |
| Ovarian Cancer | 6.0% | 5 |
| Pancreatic Cancer | 3.6% | 3 |
| Prostate Cancer | 11.9% | 10 |
| Thyroid Cancer | 2.4% | 2 |
| Other | 10.7% | 9 |
| Skip This Question | 1.2% | 1 |
| | **answered question** | **84** |
| | **skipped question** | **253** |

**3. Did your Physician inform you about experimental drugs or clinical trials that are treatment options for your type of cancer? [Discutio tu medico sobre algun estudio clinico que podia ser una option de tratamiento para tu tipo de cancer]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 33.8% | 27 |
| No | 52.5% | 42 |
| Skip This Question | 13.8% | 11 |
| answered question | | 80 |
| skipped question | | 257 |

**4. Did you conduct your own research with regard to your disease? [Buscaste information sobre tu tipo de cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 59.0% | 46 |
| No | 30.8% | 24 |
| Skip This Question | 10.3% | 8 |
| answered question | | 78 |
| skipped question | | 259 |

**5. Did you search for clinical trials as a treatment option for your disease? [Buscaste information sobre estudios clinicos para tu tipo de cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 37.8% | 17 |
| No | 60.0% | 27 |
| Skip This Question | 2.2% | 1 |
| answered question | | 45 |
| skipped question | | 292 |

**6. Which site you search information about cancer? [Donde buscate informacion sobre cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| **American Cancer Society** | **60.9%** | **28** |
| Cancer Centers or Cancer Institutes such University Hospitals | 26.1% | 12 |
| Cancer Information World | 8.7% | 4 |
| FDA website (Food and Drug Administration) | 13.0% | 6 |
| Just Search by the Name of the Disease [Busque por el nombre del cancer] | 50.0% | 23 |
| Medicine Net | 6.5% | 3 |
| National Cancer Institute (NCI) | 17.4% | 8 |
| The American Association for Cancer Research (AACR) | 8.7% | 4 |
| Web MD | 28.3% | 13 |
| Wikipidia | 15.2% | 7 |
| Others [Otra fuente de informacion] | 17.4% | 8 |
| Skip This Question | 2.2% | 1 |
| | Which others [Cuales otros] | 3 |
| | **answered question** | **46** |
| | **skipped question** | **291** |

**7. Do you know what the IT-101 or CRLX101 is in relation to cancer- solid tumors? [Sabes que es IT-101 o CRLX101 para tumores cancerosos?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes, My Doctor explained it [Si, me explico mi doctor] | 1.3% | 1 |
| Yes, I found out that information [Si, encontre esa informacion] | 1.3% | 1 |
| No | 89.7% | 70 |
| Skip This Question | 7.7% | 6 |
| answered question | | 78 |
| skipped question | | 259 |

**8. Do you know what the "I SPY Trial" is? [Sabes lo que es el estudio I SPY Trial?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes, My Doctor explained it [Si, mi doctor me explico] | 3.9% | 3 |
| Yes, I found out that information [Si, encontre esa informacion] | 3.9% | 3 |
| No | 90.8% | 69 |
| Skip This Question | 1.3% | 1 |
| answered question | | 76 |
| skipped question | | 261 |

**9. Do you search the FDA website? [Visitas el website de FDA?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 30.6% | 94 |
| No | 67.8% | 208 |
| Skip This Question | 1.6% | 5 |
| answered question | | 307 |
| skipped question | | 30 |

**10. Does the FDA website provide information about CANCER clinical trials? [Y el website de FDA tiene informacion sobre estudios clinicos para cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 10.4% | 32 |
| No | 3.6% | 11 |
| I do not know [No se] | 82.1% | 252 |
| Skip This Question | 3.9% | 12 |
| answered question | | 307 |
| skipped question | | 30 |

Chi-Square 1- Effect of Cancer Patients in "Search the FDA website"

```
Tabulated statistics: Search the FDA web site, Cancer Patients
Using frequencies in Frequency
Rows: Search the FDA web site   Columns: Sample

        Cancer      Non-Cancer
       Patient      Patient        All

No          45         163         208
         64.29       70.26       68.87
         48.21      159.79      208.00

Yes         25          69          94
         35.71       29.74       31.13
         21.79       72.21       94.00

All         70         232         302
        100.00      100.00      100.00
         70.00      232.00      302.00

Cell Contents:      Count
                    % of Column
                    Expected count

Pearson Chi-Square = 0.895, DF = 1, P-Value = 0.344
Likelihood Ratio Chi-Square = 0.880, DF = 1, P-Value = 0.348
Fisher's exact test: P-Value =  0.377805
```

Chi-Square 2- Effect of Cancer Patients in "Awareness of Clinical Trials listed in FDA's website"

```
Tabulated statistics: Awareness of Clinical Trials
information in FDA website, Cancer Patients

Using frequencies in Frequency
Rows: Awareness of CT in FDA web site   Columns: Sample
        Cancer      Non-Cancer
       Patient     Patient        All
No          55         197        252
         88.71       88.74       88.73
         55.01      196.99      252.00
Yes          7          25          32
         11.29       11.26       11.27
          6.99       25.01       32.00
All         62         222         284
        100.00      100.00      100.00
         62.00      222.00      284.00

Cell Contents:      Count
                    % of Column
                    Expected count

Pearson Chi-Square = 0.000, DF = 1, P-Value = 0.995
Likelihood Ratio Chi-Square = 0.000, DF = 1, P-Value = 0.995
Fisher's exact test: P-Value =  1
```

Appendix F

Scientists Filtered Responses

Chi-Square Calculations

-Tendency to search the FDA's website

-Awareness that the FDA's website list cancer clinical trials

## Appendix 1

SurveyMonkey

**1. What is your current and primary occupation? If presently unemployed, what was your most recent occupation? [En que trabajas?, Si estas desempleado en que trabajabas?]**

| | Response Percent | Response Count |
|---|---|---|
| Accountant [Contabilidad] | 0.0% | 0 |
| Administrative Assistant [Secretarial] | 0.0% | 0 |
| Architect [Arquitectura] | 0.0% | 0 |
| Bookkeepers [Mantiene los libros de cuentas] | 0.0% | 0 |
| Businessperson/Executive [Negocio propio] | 0.0% | 0 |
| Butcher [Carnicero] | 0.0% | 0 |
| Caregiver [Cuida enfermos o ninos] | 0.0% | 0 |
| Cashiers [Cajero/a] | 0.0% | 0 |
| Chef/Cook/Baker/Fast Food [Cocinero/ preparador de comida rapida] | 0.0% | 0 |
| Cleaning Maintenance [Limpieza] | 0.0% | 0 |
| Computer-Any field [Cualquier campo en Computadoras] | 0.0% | 0 |
| Construction [Construccion] | 0.0% | 0 |
| Customer service [Servicio al cliente] | 0.0% | 0 |
| Driver Bus/Taxi/Truck [Chofer] | 0.0% | 0 |
| Economist | 0.0% | 0 |
| Electrician | 0.0% | 0 |
| Engineer [Ingeniero] | 0.0% | 0 |

| | | |
|---|---|---|
| Farmer [Agricultor] | 0.0% | 0 |
| Fisherman [Pescador] | 0.0% | 0 |
| Flight Attendant [Asistente de Vuelos] | 0.0% | 0 |
| Garbageman [Collector de basura] | 0.0% | 0 |
| Hairdresser [Estilista] | 0.0% | 0 |
| Journalist [Reportero/a] | 0.0% | 0 |
| Laborer [Empleado de produccion] | 0.0% | 0 |
| Landscaping [Jardinero/a] | 0.0% | 0 |
| Law [Leyes] | 0.0% | 0 |
| Mechanic [Mecanico] | 0.0% | 0 |
| Medical Assistant [Asistente medico] | 0.0% | 0 |
| Miner [Minero] | 0.0% | 0 |
| Musician [Musico] | 0.0% | 0 |
| Nurse [Enfermeria] | 0.0% | 0 |
| Painter [Pintor] | 0.0% | 0 |
| Photographer [Fotografo] | 0.0% | 0 |
| Physical Therapy [Terapista fisico] | 0.0% | 0 |
| Physician [Doctor] | 0.0% | 0 |
| Physician-Infectious Disease [Doctor de Enfermedades Infecciosas] | 0.0% | 0 |
| Physician-Oncology [Doctor de Oncologia] | 0.0% | 0 |
| Pilot [Piloto] | 0.0% | 0 |
| Plumber [Plomero] | 0.0% | 0 |
| Police Officer [Policia] | 0.0% | 0 |

| | | |
|---|---|---|
| Politician | 0.0% | 0 |
| Prison Officer/Warder [Guardia o Jefe de la Prision] | 0.0% | 0 |
| Receptionist [Recepcionista] | 0.0% | 0 |
| Retail Salesperson [Vendedor] | 0.0% | 0 |
| Sales Representative [Representante de ventas] | 0.0% | 0 |
| **Scientist-Any field** | **100.0%** | **61** |
| Staying at Home Parent [Padre/madre en la casa para cuidar los hijos] | 0.0% | 0 |
| Soldier [Soldado] | 0.0% | 0 |
| Student [Estudiante] | 0.0% | 0 |
| Teacher/Professor [Maestro/a de escuela o universidad] | 0.0% | 0 |
| TV/Movies-Any field | 0.0% | 0 |
| Waiter/Waitresses [Mesero/a] | 0.0% | 0 |
| Writer [Escritor/a] | 0.0% | 0 |
| Other | 0.0% | 0 |
| | **answered question** | **61** |
| | **skipped question** | **0** |

**2. Do you search the FDA website? [Visitas el website de FDA?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 71.7% | 43 |
| No | 25.0% | 15 |
| Skip This Question | 3.3% | 2 |
| answered question | | 60 |
| skipped question | | 1 |

**3. Does the FDA website provide information about CANCER clinical trials? [Y el website de FDA tiene informacion sobre estudios clinicos para cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 23.3% | 14 |
| No | 5.0% | 3 |
| I do not know [No se] | 66.7% | 40 |
| Skip This Question | 5.0% | 3 |
| answered question | | 60 |
| skipped question | | 1 |

Chi-Square 1- Effect of Scientists subset in "Search the FDA website"

```
Tabulated statistics: Search the FDA website- Scientists
Using frequencies in Frequency
Rows: Search   Columns: Sample
       Non-Scientist  Scientist     All
No               193         15     208
                79.10      25.86   68.87
                168.05      39.95  208.00
Yes               51         43      94
                20.90      74.14   31.13
                75.95      18.05   94.00
All              244         58     302
                100.00     100.00  100.00
                244.00      58.00  302.00
                Cell Contents:      Count
                      % of Column
                      Expected count
Pearson Chi-Square = 61.951, DF = 1, P-Value = 0.000
Likelihood Ratio Chi-Square = 58.063, DF = 1, P-Value = 0.000
Fisher's exact test: P-Value =  0.0000000
```

Chi-Square 2- Effect of Scientists in "Awareness of Clinical Trials listed in FDA's website"

```
 Using frequencies in Frequency
Rows: Trials in FDA site   Columns: Sample
       Non-Scientist  Scientist     All
Do not know      212         40     252
                92.17      74.07   88.73
                204.08      47.92  252.00
Yes              18          14      32
                7.83       25.93   11.27
                25.92       6.08   32.00
All              230         54     284
                100.00     100.00  100.00
                230.00      54.00  284.00
Cell Contents:      Count% of Column
                    Expected count
Pearson Chi-Square = 14.330, DF = 1, P-Value = 0.000
Likelihood Ratio Chi-Square = 11.901, DF = 1, P-Value = 0.001
Fisher's exact test: P-Value =  0.0005346
```

Appendix G

Chi-Square Calculations

-Tendency to search the FDA's website

-Awareness that the FDA's website list cancer clinical trials

Gender Filtered Responses

**Active Filter:** Gender

**Filtered:** Female 198

Male 132

## Appendix 1

SurveyMonkey

### 1. Your gender

| | Response Percent | Response Count |
|---|---|---|
| Male [masculino] | 0.0% | 0 |
| **Female [femenino]** | **100.0%** | **198** |
| Skip This Question | 0.0% | 0 |
| | **answered question** | **198** |
| | **skipped question** | **0** |

### 2. Do you search the FDA website? [Visitas el website de FDA?]

| | Response Percent | Response Count |
|---|---|---|
| Yes | 27.1% | 49 |
| **No** | **70.2%** | **127** |
| Skip This Question | 2.8% | 5 |
| | **answered question** | **181** |
| | **skipped question** | **17** |

**3. Does the FDA website provide information about CANCER clinical trials? [Y el website de FDA tiene informacion sobre estudios clinicos para cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 7.7% | 14 |
| No | 2.2% | 4 |
| I do not know [No se] | 85.1% | 154 |
| Skip This Question | 5.0% | 9 |
| answered question | | 181 |
| skipped question | | 17 |

## Appendix 1

SurveyMonkey

### 1. Your gender

| | Response Percent | Response Count |
|---|---|---|
| Male [masculino] | 100.0% | 26 |
| Female [femenino] | 0.0% | 0 |
| Skip This Question | 0.0% | 0 |
| answered question | | 26 |
| skipped question | | 0 |

### 2. Do you search the FDA website? [Visitas el website de FDA?]

| | Response Percent | Response Count |
|---|---|---|
| Yes | 37.5% | 9 |
| No | 62.5% | 15 |
| Skip This Question | 0.0% | 0 |
| answered question | | 24 |
| skipped question | | 2 |

**3. Does the FDA website provide information about CANCER clinical trials? [Y el website de FDA tiene informacion sobre estudios clinicos para cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 20.8% | 5 |
| No | 12.5% | 3 |
| I do not know [No se] | 62.5% | 15 |
| Skip This Question | 4.2% | 1 |
| answered question | | 24 |
| skipped question | | 2 |

Chi-Square -Effect of Gender in "Search the FDA website"

**Tabulated statistics: Search FDA website by Gender**
Using frequencies in Frequency
Rows: Search FDA website  Columns: Sample

| | Female | Male | All |
|---|---|---|---|
| No | 127 | 78 | 205 |
| | 72.16 | 63.41 | 68.56 |
| | 120.7 | 84.3 | 205.0 |
| Yes | 49 | 45 | 94 |
| | 27.84 | 36.59 | 31.44 |
| | 55.3 | 38.7 | 94.0 |
| All | 176 | 123 | 299 |
| | 100.00 | 100.00 | 100.00 |
| | 176.0 | 123.0 | 299.0 |

Cell Contents: Count
% of Column
Expected count

Pearson Chi-Square = 2.568, DF = 1, P-Value = 0.109
Likelihood Ratio Chi-Square = 2.552, DF = 1, P-Value = 0.110
Fisher's exact test: P-Value = 0.128869

Chi-Square- Effect of Gender in "Awareness of Clinical Trials listed in FDA's website"

Tabulated statistics **Awareness FDA website providing Clinical Trials information** by Gender

Using frequencies in Frequency
Rows: Awareness of CT in FDA web site  Columns: Sample

| | Female | Male | All |
|---|---|---|---|
| No | 154 | 95 | 249 |
| | 91.67 | 84.07 | 88.61 |
| | 148.9 | 100.1 | 249.0 |
| Yes | 14 | 18 | 32 |
| | 8.33 | 15.93 | 11.39 |
| | 19.1 | 12.9 | 32.0 |
| All | 168 | 113 | 281 |
| | 100.00 | 100.00 | 100.00 |
| | 168.0 | 113.0 | 281.0 |

Cell Contents: Count
% of Column
Expected count

Pearson Chi-Square = 3.863, DF = 1, P-Value = 0.049
Likelihood Ratio Chi-Square = 3.780, DF = 1, P-Value = 0.052
Fisher's exact test: P-Value = 0.0566893

# Appendix H

## Chi-Square Calculations

-Tendency to search the FDA's website

-Awareness that the FDA's website list cancer clinical trials

## Age Range 31-50 years Filtered Responses

**Active Filter:** Age Range 31-50 years old

**Filtered:** 215

## Appendix 1

SurveyMonkey

### 1. Your age (choose a range only if you do not mind) [Cual es tu edad]

| | Response Percent | Response Count |
|---|---|---|
| Less than 18 years old | 0.0% | 0 |
| Older than 18 years | 0.0% | 0 |
| 18-30 years | 0.0% | 0 |
| **31-50 years** | **100.0%** | **215** |
| 50-100 years | 0.0% | 0 |
| | **answered question** | **215** |
| | **skipped question** | **0** |

### 2. Do you search the FDA website? [Visitas el website de FDA?]

| | Response Percent | Response Count |
|---|---|---|
| Yes | 34.7% | 69 |
| **No** | **63.8%** | **127** |
| Skip This Question | 1.5% | 3 |
| | **answered question** | **199** |
| | **skipped question** | **16** |

**3. Does the FDA website provide information about CANCER clinical trials? [Y el website de FDA tiene informacion sobre estudios clinicos para cancer?]**

| | | Response Percent | Response Count |
|---|---|---|---|
| Yes |  | 10.1% | 20 |
| No |  | 4.5% | 9 |
| I do not know [No se] |  | 80.3% | 159 |
| Skip This Question |  | 5.1% | 10 |
| | | answered question | 198 |
| | | skipped question | 17 |

Chi-Square 1-Effect of Age 31-50 years old in "Search the FDA website"

**Tabulated statistics: Search FDA website, Age**

Using frequencies in Frequency

Rows: Search FDA website  Columns: Sample

| | 31-50 years old | Out of 31-50 years old | All |
|---|---|---|---|
| No | 127 | 81 | 208 |
| | 64.80 | 76.42 | 68.87 |
| | 135.0 | 73.0 | 208.0 |
| Yes | 69 | 25 | 94 |
| | 35.20 | 23.58 | 31.13 |
| | 61.0 | 33.0 | 94.0 |
| All | 196 | 106 | 302 |
| | 100.00 | 100.00 | 100.00 |
| | 196.0 | 106.0 | 302.0 |

Cell Contents: Count
% of Column
Expected count

Pearson Chi-Square = 4.332, DF = 1, P-Value = 0.037
Likelihood Ratio Chi-Square = 4.447, DF = 1, P-Value =0.035
Fisher's exact test: P-Value = 0.0383557

Chi-Square 2-Effect of Age "Awareness of Clinical Trials listed in FDA's website"

**Tabulated statistics: Awareness FDA website providing Clinical Trials information, Age range 31-50 years old**

Using frequencies in Frequency

Rows: Awareness FDA website providing  Columns: Sample

| | 31-50 years old | Out of 31-50 years old | All |
|---|---|---|---|
| No | 159 | 93 | 252 |
| | 88.83 | 88.57 | 88.73 |
| | 158.8 | 93.2 | 252.0 |
| Yes | 20 | 12 | 32 |
| | 11.17 | 11.43 | 11.27 |
| | 20.2 | 11.8 | 32.0 |
| All | 179 | 105 | 284 |
| | 100.00 | 100.00 | 100.00 |
| | 179.0 | 105.0 | 284.0 |

Cell Contents: Count
% of Column
Expected count

Pearson Chi-Square = 0.004, DF = 1, P-Value = 0.948
Likelihood Ratio Chi-Square = 0.004, DF = 1, P-Value = 0.948
Fisher's exact test: P-Value = 1

# Appendix I

Chi-Square Calculations

-Tendency to search the FDA's website

-Awareness that the FDA's website list cancer clinical trials

## Location Filtered Response

**Active Filter:** GA FL PR

**Filtered:** 263

## Appendix 1

SurveyMonkey

### 1. US location where you live [Donde vives]

| | | Response Percent | Response Count |
|---|---|---|---|
| Alabama | | 0.0% | 0 |
| Alaska | | 0.0% | 0 |
| American Samoa | | 0.0% | 0 |
| Arizona | | 0.0% | 0 |
| Arkansas | | 0.0% | 0 |
| California | | 0.0% | 0 |
| Colorado | | 0.0% | 0 |
| Connecticut | | 0.0% | 0 |
| Delaware | | 0.0% | 0 |
| District of Columbia | | 0.0% | 0 |
| Florida |  | 9.9% | 26 |
| **Georgia** |  | **53.6%** | **141** |
| Guam | | 0.0% | 0 |
| Hawaii | | 0.0% | 0 |
| Idaho | | 0.0% | 0 |
| Illinois | | 0.0% | 0 |
| Indiana | | 0.0% | 0 |
| Iowa | | 0.0% | 0 |
| Kansas | | 0.0% | 0 |
| Kentucky | | 0.0% | 0 |
| Louisiana | | 0.0% | 0 |

| | | | |
|---|---|---|---|
| Maine | | 0.0% | 0 |
| Maryland | | 0.0% | 0 |
| Massachusetts | | 0.0% | 0 |
| Michigan | | 0.0% | 0 |
| Minnesota | | 0.0% | 0 |
| Mississippi | | 0.0% | 0 |
| Missouri | | 0.0% | 0 |
| Montana | | 0.0% | 0 |
| Nebraska | | 0.0% | 0 |
| Nevada | | 0.0% | 0 |
| New Hampshire | | 0.0% | 0 |
| New Jersey | | 0.0% | 0 |
| New Mexico | | 0.0% | 0 |
| New York | | 0.0% | 0 |
| North Carolina | | 0.0% | 0 |
| North Dakota | | 0.0% | 0 |
| Northern Marianas Islands | | 0.0% | 0 |
| Ohio | | 0.0% | 0 |
| Oklahoma | | 0.0% | 0 |
| Oregon | | 0.0% | 0 |
| Pennsylvania | | 0.0% | 0 |
| Puerto Rico |  | 36.5% | 96 |
| Rhode Island | | 0.0% | 0 |
| South Carolina | | 0.0% | 0 |
| South Dakota | | 0.0% | 0 |
| Tennessee | | 0.0% | 0 |

| | | |
|---|---|---|
| Texas | 0.0% | 0 |
| Utah | 0.0% | 0 |
| Vermont | 0.0% | 0 |
| Virginia | 0.0% | 0 |
| Virgin Islands | 0.0% | 0 |
| Washington | 0.0% | 0 |
| West Virginia | 0.0% | 0 |
| Wisconsin | 0.0% | 0 |
| Wyoming | 0.0% | 0 |
| No USA resident | 0.0% | 0 |
| | answered question | 263 |
| | skipped question | 0 |

**2. Do you search the FDA website? [Visitas el website de FDA?]**

| | | Response Percent | Response Count |
|---|---|---|---|
| Yes |  | 29.8% | 73 |
| No |  | 68.6% | 168 |
| Skip This Question |  | 1.6% | 4 |
| | | answered question | 245 |
| | | skipped question | 18 |

**3. Does the FDA website provide information about CANCER clinical trials? [Y el website de FDA tiene informacion sobre estudios clinicos para cancer?]**

| | Response Percent | Response Count |
|---|---|---|
| Yes | 11.1% | 27 |
| No | 2.5% | 6 |
| I do not know [No se] | 83.6% | 204 |
| Skip This Question | 2.9% | 7 |
| answered question | | 244 |
| skipped question | | 19 |

Chi-Square 1-Effect of Location in "Search the FDA website"

**Tabulated statistics: Search FDA website-Location (FL GA PR)**

Using frequencies in Frequency
Rows: Search FDA website  Columns: Sample

| | FL GA PR | The rest of USA | All |
|---|---|---|---|
| No | 168 | 40 | 208 |
| | 69.71 | 65.57 | 68.87 |
| | 165.99 | 42.01 | 208.00 |
| Yes | 73 | 21 | 94 |
| | 30.29 | 34.43 | 31.13 |
| | 75.01 | 18.99 | 94.00 |
| All | 241 | 61 | 302 |
| | 100.00 | 100.00 | 100.00 |
| | 241.00 | 61.00 | 302.00 |

Cell Contents: Count
% of Column
Expected count

Pearson Chi-Square = 0.388, DF = 1, P-Value = 0.533
Likelihood Ratio Chi-Square = 0.383, DF = 1, P-Value = 0.536
Fisher's exact test: P-Value = 0.538866

Chi-Square 2-Effect of Location in "Awareness of Clinical Trials listed in FDA's website"

**Tabulated statistics: Awareness FDA website providing Clinical Trials information, Location (FL GA PR)**

Using frequencies in Frequency
Rows: Search FDA website  Columns: Sample

| | FL GA PR | The rest of USA | All |
|---|---|---|---|
| Do not know | 207 | 45 | 252 |
| | 88.46 | 90.00 | 88.73 |
| | 207.63 | 44.37 | 252.00 |
| Yes | 27 | 5 | 32 |
| | 11.54 | 10.00 | 11.27 |
| | 26.37 | 5.63 | 32.00 |
| All | 234 | 50 | 284 |
| | 100.00 | 100.00 | 100.00 |
| | 234.00 | 50.00 | 284.00 |

Cell Contents: Count
% of Column
Expected count

Pearson Chi-Square = 0.098, DF = 1, P-Value = 0.755
Likelihood Ratio Chi-Square = 0.100, DF = 1, P-Value = 0.752
Fisher's exact test: P-Value = 1