Generational Value Differences Impacting the Perceptions of and Willingness for Clinical Trial Participation

by

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Research Project
Submitted to the School of Health Sciences
Eastern Michigan University
in partial fulfillment of the requirements

for the degree of

MASTER OF SCIENCE
in
Clinical Research Administration

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November 7, 2014
Ypsilanti, Michigan
Acknowledgements

I would like to thank Dr. Kenneth Getz and the Center for Information and Study on Clinical Research Participation (CISCRP) for their generosity in granting me permission to utilize the results of their research efforts.

Notably, I would like to Dr. Irwin Martin for his genuine spirit, kind heart, and patient support of me throughout my academic and research endeavors – and for that, I am forever grateful.
Abstract

Subject recruitment for clinical trial participation presents as a significant problem and is the primary reason for drug development delays. Data from the Center for Information and Study on Clinical Research Participation (CISCRP) Perceptions and Insight study, indicate that the 18 – 34 year old, Generation Y, subgroup were the least willing to participate in a clinical trial. Statistically significant differences exist between Generation Y compared to older age groups. Generational perceptions and value differences were explored via corporate and sociological research findings to determine why disparities exist among age groups regarding the willingness for clinical trial participation. Preliminary results, however, indicate that the findings are truly generational and not simply age-related.

*Keywords: Generation Y, clinical trial participation, medical research study*
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Chapter 1: Introduction and Background

In the quest for new drug development, human subject recruitment for clinical trial participation is a significant problem in the biomedical industry, causing untimely delays, financial setbacks, and the frequent need for global outsourcing (Trauth, Musa, Siminoff, Jewell, & Ricci, 2000). The pharmaceutical industry spends an average of $45 billion dollars on research and development, with at least 40% of this sum dedicated to conducting clinical trials (Petryna, 2009). The primary reason for clinical trial delays is due to challenges in patient recruitment (Findlay, 2009). Consequentially, as of 2005, an average of 40% of pharmaceutical and biotech clinical trials were conducted in developing countries (Petryna, 2009).

Yet, according to CenterWatch, 94% of people recognize the importance of participating in clinical research, and as many as 87% of the general population are willing to participate in a clinical research study (The Center for Information and Study on Clinical Research Participation [CISCRP], 2013). Additionally, a 2004 Research America Health Poll, reports 68% of respondents believe clinical research is of great value, and 55% of respondents indicated they would likely participate in a medical research study (Woolley & Propst, 2005). However, the 2013 CISCRP survey revealed that persons between the ages of 18 to 34 were the least willing to participate in a clinical research study (see Figure 1). This subgroup represents the Generation Y population. By viewing this problem in relation to society’s hope to advance global healthcare initiatives - the future of recruiting potential clinical trial participants is unknown.

The current literature offers many reasons why people participate in clinical trials. For example, according to a CenterWatch survey, respondents cited finding a relief or
cure (60%), helping advance science (23%), earning extra money (11%), and receiving better medical care (6%) as the top reasons for participating in a clinical trial (Getz & Borfitz, 2003). Motivations for clinical trial participation are also reinforced globally, to include wanting therapeutic options, financial compensation, access to ancillary care, curiosity or scientific interest, and demonstrating altruism (Nappo, Iafrate, Sanchez, 2013; Stunkel & Grady, 2011).

Additionally, many studies have been conducted outlining reasons why eligible participants would not want to participate in a clinical trial – examples include not wanting a placebo, concern over side effects and potential risks, worries about loss of treatment upon trial completion, utilization of current standard treatments, inconvenience, and unanticipated costs (Getz & Borfitz, 2003; Brintnall-Karabelas, Sung, Cadman, Squires, Whorton, & Pao, 2011). There are even studies that explore the decision-making processes potential subjects apply when determining whether or not to participate in a clinical trial (Guadagnolai & Ward, 1998; Verheggen, Nieman, & Jonkers, 1998).
**Figure 1.** Willingness to Participate in a Clinical Research Study – Not At All Willing

![Chart](chart.png)

*Figure 1. Graphical representation of survey respondent data stating respondents are “not at all willing” to participate in a clinical research study. Adapted from The Center for Information & Study on Clinical Research Participation (CISCRP), 2013, *2013 Perceptions and insights study: Public and patient perceptions of clinical research*. Retrieved on November 15, 2013, from [http://www.ciscrp.org/professional/reports/](http://www.ciscrp.org/professional/reports/)*
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Statement of the Problem

Understanding these data is of utmost importance, yet, there has been no identifiable research evaluating the reasons why differences exist among age groups regarding the perceptions of and willingness for clinical trial participation. The biomedical research industry would benefit from engaging in a directive to increase participation in clinical trials. Healthcare and research communities are placing greater emphasis on individual preferences by initiating patient-centered practices, establishing meaningful patient-physician relationships, and personalizing information - for instance, during the informed consent process (Siegal, Bonnie, Appelbaum, 2012; Epstein & Peters, 2009; Brintnall et al., 2011). However, recognizing factors, such as generational values, that influence prospective subjects’ decision-making processes may potentially provide the framework necessary for prosperous subject recruitment and clinical trial participation (Brintnall et al., 2011).

Purpose and Significance

According to White (2013), generational thinking is important to understand by directing attention to the intent and various elements that influence the context of perceptions and basis for choices. As perceptions shape willingness, this includes viewing generationalism in the milieu of clinical trial participation.

The primary objective of this study was to analyze the 2013 CISCRP survey for age-based data to determine if statistically significant differences exist among the 18 – 34 year old, Generation Y subgroup, compared to older age groups regarding willingness to participate in a clinical trial. Secondary objectives include exploring Generation Y value differences that may impact the perception of clinical trial participation. As such, this
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information may contribute to the body of knowledge the biomedical research community has concerning human subject recruitment within this age group as future participants of clinical trials.

**Hypothesis**

It is hypothesized, based upon the media-hyped life-experiences, individualistic attitudinal differences, and defining generational characteristics, that Generation Y will represent statistically significant differences in their willingness to participate in a clinical trial compared to older age groups or generations.

**Limitations**

It is unreasonable to suggest the only factor impacting the perceptions of and willingness for clinical trial participation is generational value differences among distinct age groups. Rather, there are many variables which may influence a person’s desire to be involved in a clinical trial - such as, individual motives, life span development, and health status - just to name a few.
Chapter 2: Literature Review

A generation is formalized as a distinct cohort of people who share birth years, age, and unique historical, political, economic, and social life experiences at critical developmental life stages. These shared commonalities and viewpoints help define the uniqueness and character of each generation (Carlson, 2009). As a result of these social categorizations, perspectives are formed and shaped which inspire mindsets toward authority, organizations/industries, and work, as well as how to respond to and satisfy problems (Smola & Sutton, 2002; White, 2013). This includes, for instance, Generation Y’s viewpoint on healthcare initiatives and the clinical research enterprise.

Generation Y is a cohort of society born between 1979 and 2000, placing these individuals, at present day, to be 14 to 34 years of age. The birth year range varies slightly by author, but overall, this date range classifies Generation Y. A summary of distinctive characteristics for this generation include, information seeking and media/technology savvy, demonstrating a robust work ethic with an emphasis on individualism, accepting change and transition adequately, displaying efforts to create a more cultured, educated, and tolerant society, exhibiting a high self-regard, and a belief of self-entitlement and instant gratification (Jorgenson, 2003; Ng, Schweitzer, & Lyons, 2010).

Prominent historical, political, and economic occurrences experienced by this generation during principle developmental milestones and vulnerable formative times consist of exceptional numbers of media-sensationalized events (see Table 1). For example, Generation Y observed and/or experienced the effects of the financial and housing catastrophe, fraud and deception from major corporations, terrorism,
controversial government practices, natural disasters, schoolyard shootings, and numerous high-profile pharmaceutical and medical device company recalls, just to name a few. Moreover, this social media society has constantly been inundated with advertisements fraught with individuals portrayed as victims of scams – drug and device related deaths and recalls, occupational hazard exposures, and corporate class action law suits.
**Table 1.** Historical Events Experienced by Generation Y during Critical Developmental Years

<table>
<thead>
<tr>
<th>Event</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. involvement in Gulf War (Operation Desert Shield)</td>
<td>1990</td>
</tr>
<tr>
<td>51-day Waco, Texas standoff (cult members and federal agents killed)</td>
<td>1993</td>
</tr>
<tr>
<td>Oklahoma City domestic terrorism bombings (168 people killed)</td>
<td>1995</td>
</tr>
<tr>
<td>Columbine school massacre</td>
<td>1999</td>
</tr>
<tr>
<td>September 11: Islamic fundamentalist terrorists attacks on U.S.</td>
<td>2001</td>
</tr>
<tr>
<td>U.S. initiates War on Terrorism against the Taliban and Al-Qaida</td>
<td>2001</td>
</tr>
<tr>
<td>Enron scandal</td>
<td>2001</td>
</tr>
<tr>
<td>Southeast Asian tsunami (290,000 people die)</td>
<td>2004</td>
</tr>
<tr>
<td>Drug recalls (Cox-2 inhibitors, i.e., Vioxx)</td>
<td>2004</td>
</tr>
<tr>
<td>Hurricane Katrina</td>
<td>2005</td>
</tr>
<tr>
<td>Subprime mortgage crisis</td>
<td>2007</td>
</tr>
<tr>
<td>Barack Obama takes oath as first African-American U.S. president</td>
<td>2009</td>
</tr>
</tbody>
</table>
Chapter 3: Research Background and Methodology

The Center for Information and Study on Clinical Research Participation (CISCRP) was established in 2003 as an “independent, Boston-based, globally focused nonprofit organization,” focusing on educational initiatives, which include clinical research education programs, public service campaigns, educational media, clinical trial search technologies, and clinical trial communication programs. CISCRP also conducts research studies intended to understand societal perceptions of clinical trials to provide practical “insight into actionable ways that clinical research professionals can better understand, and more effectively engage with, the public and study volunteers” (CISCRP, 2013).

Approved by an ethical review committee, and based upon the input and support from pharmaceutical, biotechnology, contract research organizations, and investigative sites, CISCRP conducted an online international survey between January and March 2013, titled, “The 2013 CISCRP Perceptions & Insights Study: Report on General Perceptions.” The study objectives were aimed towards gathering a “global assessment of public and patient perceptions, motivations, and experiences with clinical research participation in order to monitor trends and identify opportunities to better inform and engage the public and patients as stakeholders and partners in the clinical research enterprise.” Additionally, CISCRP partnered with Acurian - global provider of patient recruitment and retention services – to assist with international survey recruitment and distribution.
Method

Null Hypothesis

Generation Y will not be any less willing to participate in a medical research study when compared to older age groups.

Participants

The total number of survey respondents was N=5,701. The participants were eighteen years of age or older, of which, (75%) were North American, while the remaining participants were South American (5%), European (15%), and Asian-Pacific (5%). Additionally, 61% of respondents have never participated in a clinical trial, while 39% reported previous participation in a clinical trial.

Materials and Procedure

A quantitative subset analysis of the North American data (N=4276) was conducted from the 2013 CISCRP Perceptions and Insights Study, focusing on one question of importance, “How willing are you to participate in a clinical research study?” Of the North American participants, N=4228, responded to this question and disclosed age and education information. Survey response options were: “I am not sure,” “not at all willing,” “not very willing,” “somewhat willing,” and “very willing.” The response, “I am not sure” (N=89; 2% of participants) was omitted from the data analysis, thus revising the sample size to N=4139.

The survey responses were explained by the following age groups: 18 – 24, plus, 25 – 34 year olds (Generation Y), compared with the responses of participants ages 35 years or older (see Table 2). The total number of survey respondents representing the 18
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– 34 year old, Generation Y subgroup, (N=469) denoted 11 % of the North American study population.

The dependent variable, willingness to participate in a clinical trial, was measured on an ordinal scale consisting of four categories: 1 = not at all willing, 2 = not very willing, 3 = somewhat willing, and 4 = very willing. The appropriate method to test for a difference in mean scores between two groups made up of different individuals is the independent-samples t test. The null hypothesis in this test is that the two groups have the same mean, and a significant result rejects the null hypothesis in favor of the conclusion that the two groups are different. The independent samples t test assumes that the variability in scores is the same in both groups, an assumption that is known as “homogeneity of variance.” This assumption is often violated in practice, and hence a more conservative version of the t test is available that adjusts the degrees of freedom used in the t test to account for differences in variability. The adjusted t test will be used to assess the main hypothesis given that it requires fewer assumptions that the traditional t test.
Table 2. Number of North American Respondents by Age Group (CISCRP, 2013)

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Number of Respondents</th>
<th>Respondent Percentage (n = %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 – 24</td>
<td>121</td>
<td>3</td>
</tr>
<tr>
<td>25 – 34</td>
<td>348</td>
<td>8</td>
</tr>
<tr>
<td>35 – 44</td>
<td>638</td>
<td>15</td>
</tr>
<tr>
<td>45 – 54</td>
<td>1,032</td>
<td>24</td>
</tr>
<tr>
<td>55 – 64</td>
<td>1,253</td>
<td>30</td>
</tr>
<tr>
<td>65 – 74</td>
<td>645</td>
<td>15</td>
</tr>
<tr>
<td>75+</td>
<td>191</td>
<td>5</td>
</tr>
</tbody>
</table>
Chapter 4: Results

The mean response among 18 to 34-year olds was 3.46 (SD ± .686), and the mean response among subjects 35 and older was 3.59 (SD ± .554). This shows that average responses are lower among younger respondents compared to older ones. An independent samples t-test adjusted for unequal group variances revealed that this difference was statistically significant (t (524.21) = 3.771, p < .001), meaning that it is possible to reject the null hypothesis that the two groups are equal. Statistical significance is not always the same as clinical significance, however, so Cohen’s d was also calculated as an effect size. According to Cohen (1988), values of Cohen’s d equal to .2 or less indicate a small effect size, values around .5 indicate a medium effect size, and values around .8 indicate a large effect size. The estimate of Cohen’s d for these data was .222, indicating that the effect size was closer to the small end of the scale than the medium point.
Figure 2. Willingness to Participate in a Clinical Research Study – How Willing

Figure 2. Graphical representation of survey respondent data stating respondent’s willingness to participate in a clinical research study. Adapted from The Center for Information & Study on Clinical Research Participation (CISCRP), 2013, 2013 Perceptions and insights study: Public and patient perceptions of clinical research. Retrieved on November 15, 2013, from http://www.ciscrp.org/professional/reports/
Chapter 5: Discussion

Based upon the quantitative subset analysis of the 2013 CiscrP Perceptions and Insights Study: Public and Patient Perceptions of Clinical Research, the Generation Y subgroup did harbor a more negative view of clinical trials and were less willing to participate in a medical research study, as compared with older age groups (see Figure 2). These results are indicative of generational differences. Furthermore, these findings can be reinforced as a review of the literature revealed ancillary findings of the Trauth et al. (2000) survey conducted in 1994 (see Figure 3), which sought to determine the willingness of respondents to participate in a clinical research study. The Trauth et al. survey results were of interest to determine if the differences seen between age groups are truly generational, rather than maturational.

The 18 – 34 year olds in the 2013 CiscrP study represent Generation Y, whereas the 18 – 34 year olds in the 1994 Trauth et al. study represent Generation X due to the date in time. The results displayed in the 2013 CiscrP chart (Figure 1) represent age-based data stating the percentage of respondents “not at all willing” to participate in a clinical research study. Clearly, the Generation Y subgroup stands out yielding the highest percentage (5%) of the respondent population as least willing to contribute to the clinical research enterprise. However, in the 1994 Trauth et al. study, the then, 18 – 34 year old subgroup, classified as Generation X, represents the highest percentage of respondents (56.8%) willing to participate in a clinical research.

To acquire a more comprehensive overview of the Generation Y subset in regards to clinical trial participation, initial questions presented in the 2013 CiscrP Perceptions
and Insights Study, such as understanding what is meant by the term “clinical research study,” and rating one’s “general knowledge about clinical research” must be reviewed foundationally to delineate between age-based maturational distinctions and progress towards value differences related to clinical trial participation – such as viewing temporal aspects, social media influence, information seeking characteristics, and generational value factors. For example, the 18 – 34 year old population typically presents with fewer health conditions and concerns as compared with older persons and generations. Although, these younger individuals tend to encompass the value of health and demonstrate concern, their main focus, however, is on preventative measures, such as weight control, healthy living habits (exercise and diet), and disease prevention. Therefore, because a clinical trial is defined as a “prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions,” understanding what is meant by the term clinical research study may have fewer applicability and significance to this younger population – they are in less demand of this targeted information (NIH, 2013, para 17).
**Figure 3.** Willingness to Participate in a Clinical Research Study – 1994 Trauth

Temporal Factors

Rating one’s general knowledge of clinical research may also be temporally related. Generation Y was born between the years of 1979 – 2000. However, many of the medical breakthroughs that affected the population and had significant epidemiological consequences that took place prior to their existence. The treatment of diabetes, vaccinations for diphtheria, pertussis, tuberculosis, and tetanus, and the discovery of penicillin took place in the 1920’s. Vaccinations for yellow fever and typhus, along with blood banking, and the creation of the heart-lung machine happened in the 1930’s. The antibiotic streptomycin, vaccinations for influenza and polio, and development of the cardiac pacemaker occurred in the 1940’s and 1950’s. Vaccinations for measles, mumps, rubella, chicken pox, and pneumonia took place in the 1960’s and 1970’s (Pearson Education, 2007). Each of these medical advances produced a tangible impact for the older subgroups, while providing monumental strides in healthcare for the future generations.

Many of the aforementioned diseases had been eradicated and have not been seen or experienced by Generation Y, whereas the older age groups were and may continue to be deeply affected by these conditions. Older generations may have experienced the death of a family member due to influenza, male infertility due to mumps, or post-polio syndrome as the result of the acquiring the poliovirus as a child. Although medical breakthroughs have continued to occur throughout the known lifetime of the Generation Y subgroup, such as with the advent of vaccinations for hepatitis or the treatment of AIDS, Generation Y may have been too young to realize the epidemiological impact. Therefore, Generation Y’s lack of general knowledge about clinical research, as
compared with the older age groups may be temporally related, versus differences in generational values.

**Social Media**

As temporal factors relate to the understanding of what is meant by the term clinical research study and rating one’s knowledge about clinical research, aspects of generationalism do impact social media practice and the perception of clinical trial safety. According to CISCRP (2013), more than 60% of the 18 – 34 year old population have engaged in social media forums to learn about clinical research, and while human subject recruitment for clinical trial participation presents as a significant problem to the biomedical industry, social media usage may open many opportunities for Generation Y to uphold the importance of clinical research and continue to strive toward the pursuit of scientific advancement through education and contribution.

To help solve human subject recruitment issues, social media usage offers a valuable marketing tool for sponsors to target a wide range of demographics, especially reaching out to the Generation Y subgroup. For example, in 2014, greater than 80% of persons from Generation Y are internet-users, while more interestingly, Generation Y represented the highest percentage of internet-users (>20%) actively seeking specific information about experimental treatments or medicines (Pew Research Center, 2014). Websites, such as ClinicalTrials.gov provide information seekers with comprehensive resources to learn about clinical studies. Additionally, ClinicalTrials.gov offers users the ability to set up Rich Site Summary or Really Simple Syndication (RSS) feeds to receive trial related information and updates. However, these web-based conveniences are not social media centered and require the user to actively pursue the content.
Digital Revolution and Information Seeking

Generation Y has grown up during a digital revolution – they value the use of and are sophisticated consumers of technology – Generation Y are e-learners, therefore, websites such as ClinicalTrials.gov appears to be yet another resource in reaching this population of society (Allerton, 2001). Furthermore, in a 2013 Research America poll, 53% of survey respondents reported hearing about clinical trials via the Internet, but cited lack of trust and information as barriers to clinical trial participation.

Equipped with this information, sponsors knowingly have access to this demographic, and should use social media to educate this critical and cynical audience about the value of clinical research. To reinforce this, according to a survey of 500 Generation Y’s, 68% of Generation Y news sources are obtained via social media sources; however, 66% of this population are not confident that the news they receive is accurate (YPULSE, 2013).

Lack of confidence in information presented via social media sources may directly impact the perception of clinical trial safety, as well as present a noteworthy barrier to sponsor marketing and education. Yet, it does yield useful evidence regarding the methods of information exchange for and information-seeking behavior of this generation. They want the facts, and are willing to pursue other online resources to ensure the integrity and accuracy of the information. In fact, more than 70% of the Generation Y population use the Internet to seek information about health related issues (Pew Research Center, 2014).
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Generational Value Factors

Most importantly, why does Generation Y represent the highest percentage of the CISCRP 2013 survey respondents not at all willing or not very willing to participate in a clinical research study? Temporal factors have been explored and discussed, coupled with the generational importance placed on technology regarding the perception of clinical trials, but what are the generational thinking and value factors influencing the context of and basis for choices in the milieu of Generation Y clinical trial participation?

Overarching themes in the literature are abundant with this generation’s defining characteristics.

Generation Y has been coined by some as “Generation Me,” and has been deemed, by some reviewers, as having a pampered upbringing, serving to signify the individualistic nature of this cohort (Ng, Schweitzer, & Lyons, 2010). In a recent study evaluating generational changes in “community feeling,” Generation Y was found to have greater civic and political disengagement, more emphasis on materialistic principles, and demonstrate less concern towards helping the public at large than were Generation X and Baby Boomers at the same ages (Twenge, Campbell, & Freeman, 2012). This information is further strengthened by the 1994 Trauth et al., study findings, which show the then 18 – 34 year old subgroup (Generation X), were the most willing age group to participate in a clinical research study. Furthermore, the 18 – 34 year olds in the Trauth et al., study did not even have comparable access to the Internet for information exchange. Considering that clinical research or investigations are designed to contribute to generalizable knowledge, meaning the greater good of society, it is apparent that the
suggested individualistic values Generation Y upholds would hinder their willingness to participate in a clinical trial.

Moreover, Generation Y has been referred to as harboring a sense of self-centeredness, narcissism, and entitlement. They place greater importance on extrinsic values, as compared to intrinsic values, such as concern for others (Twenge et al., 2012). For example, in the corporate workplace, they have been cited for their inpatient nature, combined with their unrealistic expectations for career advancement, despite job performance (Ng et al., 2010). In other corporate circumstances, they need continual positive reinforcement, nurturing, and tangible recognition – to the point of companies hiring “praise teams.” Furthermore, this generational group has been in the spotlight for not taking responsibility for their own actions, while expecting others to pay the consequences of their mistakes (Aspen Education Group, 2011).

Thus, this same value system is reflective in and can be applied to and correlated with Generation Y’s lack of willingness towards clinical trial participation. In light of their perceived sense of narcissism and self-centered traits and features, Generation Y may take for granted the altruistic nature of those subjects contributing to the medical sciences – those who are bearing the burdens of clinical research - by demonstrating apathy or simply feeling entitled to reap the benefits of the research. They may lack the sense of shared responsibility or public health impact their contribution could make, yet they are very driven by creating tolerance for individualism and advocating for social change.
Chapter 6: Conclusion

The analysis of the 2013 CISCRP and 1994 Trauth et al., study findings has led to the rejection of the null hypothesis. Generational disparities do exist among age groups related to the perceptions of and willingness for clinical trial participation. Although temporal factors must be taken into account when attempting to understand why Generation Y harbors negative views of and are the least inclined cohort to participate in a clinical trial, generational value factors, versus simply age, certainly offer objective support via corporate and sociological study findings. These conclusions are not proposed to cast a negative view about Generation Y; rather, they are intended to point out some of the inequalities that exist among generations or age groups, notably viewing the impact as it relates to clinical trial participation and the future of our advancing global healthcare initiatives.
References


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