

Chapter 11

Diversifying Clinical Research Participants: The Potential Role of Health Information Technologies and Online Strategies

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ABSTRACT

The diversification of clinical trial participants to include women and minorities is one of the biggest challenges for the clinical research industry. The lack of diversity in clinical trials prevents the tailoring of healthcare interventions specifically for women and minorities. The purpose of this chapter is to explore how health information technology and online strategies can be applied in the clinical trial research process to increase the recruitment and retention of women and minorities in clinical trials. By examining this issue from both the individual (participant) and clinical stakeholder perspective, appropriate strategies utilizing available technology are proposed. In the health care environment, strategies to diversify clinical trial participants include the secondary use of Electronic Health Records, and disease registries, as well as e-learning to raise awareness and train health professionals and clinical trial staff. In order to recruit diverse participant populations, the use of online advertising, social media, e-newsletters, tablets, smartphones, and apps are detailed. Lessons from previous use of technology in recruitment are outlined as well as future trends. In summary, while there are recognized challenges to implementation, the current health information technology and online strategies available seem promising as methods of increasing the participation of women and minorities in clinical trials.

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INTRODUCTION

As the healthcare industry grows, there has been an increase in the number of clinical trials that play a key role in the prevention, intervention, and treatment of many medical conditions that affect both mental and physical health. However, one of the biggest challenges for the clinical research industry is the issue of recruitment and retention, particularly relating to women and minority populations. Although these are two separate groups, they are grouped together in this chapter as both populations are under-represented in clinical trials and similar challenges are experienced when it comes to their recruitment. Furthermore, the term minorities will be used to describe many different ethnicities and races.

It is important to understand the definition of a clinical study and the purpose of conducting this type of research. A clinical study is research conducted with human volunteers who are also called subjects or participants, with the intent of contributing to medical knowledge (National Institutes of Health, 2015). For purposes of this chapter, the term participants will be used. The Food and Drug Administration (FDA) categorizes clinical trials by Phases I-IV, which are categories for describing the characteristics of the study based on its objectives and number of participants. For example, a Phase I clinical trial typically requires the least number of participants and is usually focused on evaluating the safety profile of a treatment. On the other hand, a Phase IV clinical trial is when the treatment becomes marketed, and thus, is available for use to the wider population the treatment is intended for, while allowing for the collection of long-term use safety data.

Every clinical trial has a specific planned design explaining how the study will be conducted and why, which is also known as the protocol. The study is typically carried out by investigative sites, teams of healthcare professionals, and led by principal investigators. Consequently, the principal investigator, often a medical doctor, plays

a key leadership role in the clinical trial process, having the primary responsibilities to adhere to the protocol while helping ensure patient safety. Other stakeholders involved in sponsoring or funding clinical studies are pharmaceutical companies, academic medical centers, voluntary groups, and government organizations.

A clinical trial or intervention study is designed with the intent of enrolling a certain number participants who are to receive a specified treatment that could be a drug, procedure, or behavioral program. The general purpose of clinical trials is to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases or conditions, or to evaluate the efficacy of one or more interventions for the treatment of a disease or condition. Participants may be assigned to an intervention group where they receive a new treatment, to a control group where they receive placebo, or to no intervention (ClinicalTrials.gov, 2014).

Despite the increase in the number of clinical trials, the issue of recruiting women and minorities remains salient. The Society for Women's Health Research, FDA, and the Office of Women's Health (2011) describe this systemic issue as "Women and ethnic/racial minorities routinely and disproportionately have been excluded from medical product research throughout history" (p. 3). The National Medical Association created Project I.M.P.A.C.T to increase minority participation and awareness of clinical trials. This organization stated that "African Americans are underrepresented in important medical research to find treatments for the very diseases that affect them such as diabetes, hypertension, HIV/AIDS, and lung cancer. Your good health depends on knowing whether a treatment affects women or men differently, or affects a minority differently" (Project I.M.P.A.C.T, 2008, p.4). For women and minorities, health disparities relating to disease prevalence and risk, health care quality, and health care access are indicators that recruitment and retention practices need to change.

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