

Chapter 48

Increasing the Participation of Women and Minority Populations in Clinical Trials: Integrating Technology–Oriented Strategies into Clinical Research Practice

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ABSTRACT

Increasing the participation of women and minorities in clinical trials is a challenge for the healthcare industry. The lack of diversity in clinical trials prevents the tailoring of healthcare interventions specifically for women and minorities. The purpose of this paper is to explore how technology-oriented strategies can be applied in the clinical trial research process to increase the recruitment of women and minorities in clinical trials. An overview of clinical trials, the stakeholders, and current issues in diversifying recruitment are provided. 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. With the support of clinical trial stakeholders, the current technology-oriented strategies available seem promising as methods for increasing the participation of women and minorities in clinical trials.

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INTRODUCTION

As the healthcare industry shifts to a population health approach that focuses more on the prevention of diseases and chronic illnesses, technology continues to play a role in the delivery of care, the storing of patient records, and the tracking of health trends. In addition to the rapidly changing healthcare environment, the demographic composition of the U.S. population continues to diversify. According to the U.S. Census Bureau (2015), minorities represented 37.9% of the U.S. population as of 2014. This number is expected to continue to increase, especially when looking at the representation of minorities within younger generations. For example, in 2014 those younger than five years old became the majority-minority for the first time, representing a whopping 50.2% of the U.S. population (U.S. Census Bureau, 2015). In addition, according to the U.S. Census Bureau (2015), females made up 50.8% of the U.S. population in 2014. However, according to the U.S. Food and Drug Administration (2015), women and minorities have historically been underrepresented in clinical trials. Consequently, one of the biggest challenges for the clinical research industry is the recruitment of women and minority populations. The term minorities will be used to describe many different races including individuals who are Hispanic or Latino, Black or African American, American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, and those who are of two or more races. Not only does the adequate inclusion of women and minorities in clinical trials lead to a better understanding about how to identify and treat disorders, but it also leads to more accurate diagnoses (Ma et al., 2014). Anwari et al. (2013) stated that the “comprehensive inclusion of diverse participants in clinical trials is essential in assuring generalizability of prevention, diagnostic, and treatment recommendations” (p. 1798).

According to the National Institutes of Health (2015), clinical studies are performed with humans who have consented to participate in order to help researchers gather information on how to prevent, identify, or treat diseases and conditions. The I-IV phases of clinical trials differ in their objectives, including the number of participants that are needed in order to adequately answer the research questions. For example, a Phase IV clinical trial is typically designed to further evaluate the long-term safety effects of a treatment or intervention that is already on the market and usually reaches the largest patient pool.

STAKEHOLDERS

Every clinical trial has a specific planned design explaining how the study will be conducted and why, which is called a protocol. The protocol is used by clinical researchers to outline the design of the study along with the role that each stakeholder will play. The stakeholder that is involved in sponsoring or funding the clinical study could be a pharmaceutical company, academic medical center, voluntary group, and/or the government. The sponsor stakeholder has the overall responsibility for conducting the clinical trial. Specifically, one of the organizational aims is to meet recruitment targets (i.e., enrolling a certain number of patients in a certain period of time) in order to minimize the costs related to the conduct of the study and to be able to evaluate the results of the study within a timely manner. On the other hand, the study is typically carried out by investigative sites with teams of healthcare professionals led by principal investigators. 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 to ensure patient safety. The principal investigator, in conjunction with the other site personnel involved in the study, is responsible for identifying potential participants for a clinical trial and confirming their

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