Cancer Doesn't Discriminate. So Why Do Our Clinical Trials? A Movement for Change

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Description

The trial for clinical equality campaign was conceived to address the issue of underrepresentation of Black and Hispanic patients in cancer trials. The issue is a longstanding one that is critical to address. In a US database study, [1] explored disparity in racial and ethnic minority representation in trials supporting FDA oncology drug approvals from July 2008 to June 2018 [1]. African Americans make up 13% of the US population, yet the study reported that they make up only 3% of cancer trial patient populations; similarly, Hispanics make up 19% of the US population, yet only 6% of cancer trial patient populations [1,2]. Perhaps more relevant, however, is the disparity between minority ethnic representation in cancer trials and the estimated proportion of patients of each respective ethnicity diagnosed with that cancer in the population. This enrollment incidence disparity for all cancers together was unfavorable for Black (−11.3%) and Hispanic patients (−7.8%) compared with white (−1.7%) and Asian (+14.1%) patients. A similar pattern emerged regarding cancer mortality [1]. These striking statistics reveal a need to not only address but end racial and ethnic disparities in clinical trials.

The issue of ethnic underrepresentation appears to be prevalent–and, some might argue, is even more pronounced–in Europe. Data are sparse, however. A 2004 study found that American studies are five times more likely than European studies to report information on the ethnicity of participants, concluding that "European governments should consider the US model for promoting inclusion of ethnic minority participants in research" [3]. More recently, a 2021 report by *Blood Cancer UK* acknowledged that minority ethnic group underrepresentation in UK clinical trials has been recognized for many years [4]. An analysis of 64 studies and an English hospital trust case study found that the odds of participating in a trial were 30% lower for patients from a minority ethnic group compared with white patients with cancer (adjusted OR=0.70, range: 0.53–0.94, *P*=0.01) [5]. And in a 10-year UK outcomes study of >1600 men with prostate cancer, less than 1% of the participants were of African–Caribbean ancestry [6]. In Sweden, assessment of representation is limited by personal data regulations and laws that prohibit the collection of ethnic data [7]. However, a qualitative study demonstrated that physicians frequently exclude ethnic minority patients from clinical cancer trials, often citing language barriers as the prime underlying reason [7].

Without a representative population of clinical trial patients, the validity of the ensuing data in the real world is diminished. Underrepresentation of ethnic minorities in clinical trials inevitably leads to a skewed body of evidence: One that is neither relevant nor generalizable to many of the patients that would stand to benefit from it [4,8,9]. Enrollment of patients from diverse ethnic groups is essential to explore the existence of differential risks and benefits of therapy across them. According to a review of 167 new drugs approved by the FDA between 2008 and 2013, differences in exposure and/or response across racial/ethnic groups were evident for 1 in 5 agents. In some cases, these differences translated to population-specific prescribing recommendations that could not have been drawn from homogenous trial populations [10].

While scientific rigor is an important consideration, it is not the only one; the ethical repercussions of exclusion are substantial. Participation in clinical trials can present the opportunity to access a new treatment, which may be the best (or even only) therapeutic option available to a patient at a certain time [4]. Further, exclusion of people from minority ethnic groups may perpetuate health inequalities, marginalization, and disengagement from healthcare services as well as research [4,9].

Why are we seeing this consistent underrepresentation of ethnic minorities in clinical trials? Assumptions that this is due to a difference in willingness to participate appear to be unfounded. People *do* choose to participate when given the opportunity [4,11]. The true underlying reasons are likely to be multifactorial in nature. Guidelines from the US National Institutes of Health call for proportional racial representation in NIH-funded clinical research [1]. However, no such guidelines exist in the UK, for example, and even in the US, most trials that lead to drug approvals are funded by industry rather than the NIH [1,5]. The guidelines have not proven sufficient to address the problem.

FCB Health is committed to making health equality a reality for all people. At FCB Health, we identified the need to expand the conversation beyond the clinic. Exploring underlying blind spots and biases, we are building a social movement to eliminate disparities in clinical cancer trials: The trial for clinical equality. Partnership with key institutions and advocacy groups will be a fundamental step toward effecting necessary change and saving more lives from cancer.

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