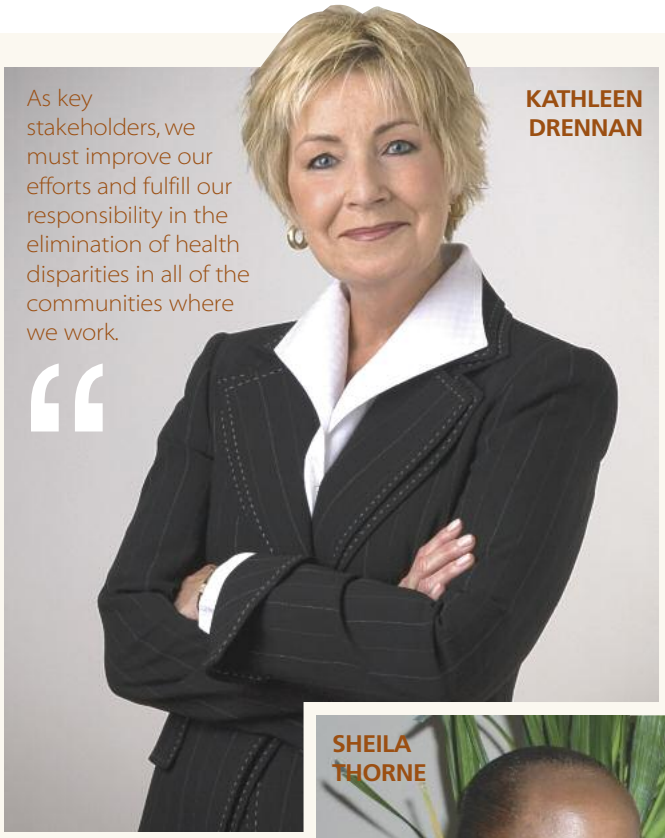
Diversity in Clinical Trials — From Rhetoric to REALITY



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Now more than ever, traditional pharmaceutical business and clinical research strategies are being put to the test. Biopharmaceutical research teams that make a consistent and conscious decision to weave multiculturalism into the fabric of the business of medicine, from biomedical research and marketing to selling prescription medicines, will discover actionable return on their investment, which will have profound global implications.

Rapidly changing demographics are shifting the texture and fabric of American society. So-called niche markets have become "minority-majority" markets. Current healthcare reform that is focusing on better outcomes will only place more pressure on study sponsors to demonstrate to regulators that their clinical trials include all of the populations that will actually use the prescription medicines and consumer health products being studied. Recruiting adequate numbers of clinical trial participants has always been difficult, particularly in women, children, and the aging populations, and it is an even a greater challenge for people of color.

Clinical research is the foundation for the practice of evidence-based medicine. The more diverse the participant pool, the more confidence there is in study results and the benefits of the medicine to all people.

Because of diversity under-representation, researchers continue to extrapolate trial data from populations who may not look like the population intended for prescription use. This could be dangerous now that scientific data are available that demonstrate how different medicines may metabolize differently or may adversely affect patient populations in different ways. The lack of diversity in clinical trials can have a significant impact on the quality of outcomes and patient survival. Poor outcomes and survival rates of diverse populations will continue to increase racial and ethnic health and healthcare disparities.

The FDA's renewed attention to the absence of diversity data is growing and will likely catch up with study sponsors when regulators demand additional postmarketing commitment studies or completely deny approval of an NDA. As key stakeholders, we must improve our efforts and fulfill our responsibility in the elimination of health disparities in all of the communities where we work.

There are several reasons why this is important. It's good business, it's good medicine, and it's the right thing to do, especially in the Unit-

ed States as access to healthcare widens. The reality is that clinical trials are the only gateway to bringing new and effective drugs to all people. As innovation in new drug therapies continues to exceed outdated or inefficient clinical trial processes and performance, large segments of the world's population are not benefitting from the science that demonstrates how diverse populations are biologically affected by or respond differently to pharmaceutical therapies. The industry is faced with unprecedented challenges to address the unique and special needs of U.S. emerging majority populations who suffer disproportionately from cancer, chronic disease, disabilities, and premature death.

Racial and ethnic groups appear to participate in clinical trials to varying degrees. Blacks participated in trials to the greatest extent; however, their participation steadily declined from 12% in 1995 to 6% in 1999. In all cases, Hispanics appear to be far below their representation in the population.

And it's not because drugs are not being developed to target diverse populations. Good news abounds in that there are more than 4,000 new drugs in pharmaceutical development looking at diseases that disproportionately affect African Americans, Hispanic Americans, women, children, and the aging populations.

Drugs "in development" is the operational phrase, and for many drugs this is synonymous with "delayed in clinical trials." The barriers, perceived and real, that prevent under-represented populations from participating in trials are well-documented. They include mistrust of the medical and research communities, lack of awareness, cultural and language differences, socioeconomic obstacles, costs, study design, implicit and explicit racial bias, institutional racism, and reimbursement policies.

It's time to move beyond the rhetoric and implement comprehensive and inclusive protocols, plans, and strategies that address known barriers, uncover others, and to facilitate and expedite enrollment of under-represented populations. By 2014, healthcare reform legislation will enable 32 million Americans — more than 50% of whom are people of color — to have access to health products and services for the first time, and yet only 2.5% of adults, and fewer racially and ethnically diverse individuals, participate in cancer trials, as an example. Increasing diversity in clinical trials is no longer an option, but a strategic clinical imperative.

National initiatives in the past two decades have addressed the issue of disparities in research participation, including the NIH Revitalization Act of 1993, which requires a strategy for inclusion of women and minorities in federally funded trials; the FDA Modernization Act of 1997, which requires standardization of data collection on racial/ethnic groups; and the 2000 Centers for Medicare/Medicaid Services provision of payment of routine care costs for Medicare beneficiaries who participate in clinical trials. Despite these efforts it is imperative the industry addresses and resolves why progress has not been made to successfully include and retain the numbers needed to qualify clinical trials as optimally diverse.

As strategies continue to grow for improved treatment and outcomes through targeted therapies it stands to reason that the industry must include early clinical trials as part of its growth strategy. Progressive and enlightened companies that lead clinical trial diversity will build new bridges with both patients and doctors. Most importantly, clinical teams that include cross-cultural analysis, ethnographic research, and integrate culturally relevant data and methodology into actionable platforms and protocols, will revolutionize the way clinical trials are developed, managed, and completed.

Reaching under-represented populations requires new skills, new mindsets, new partners, and new competencies on the part of clinical trial team leaders. It is time to discard the one-size-fits-all mentality of recruitment and retention strategies and replace them with culturally relevant strategies and tactics to successfully recruit and retain diverse patients for clinical research. A commitment to solving the diversity inclusion issue could positively affect the current concerns of deficient patient recruitment, inconsistent clinical site performance, and inadequate investigator pools, therefore accelerating trials rather than continuing with delays.

Stepping Up — What Will it Take?

Current clinical trial practices do not have to be turned on their head to ascertain change to include diverse populations. Nor does chaos have to ensue within clinical team operations. By integrating proven trial methodology with a diversity approach, trial planning can ensue quite rapidly. Although programs may vary in specificity, according to population segments and disease, strategic trial plans must be integrated across all populations, not fragmented, as a way to leverage time, resources, and cost-efficiencies.

But developing best practices to include diverse populations and diverse investigators into the trial planning and implementation process will require actionable steps and additional resources. Primary steps include:

ETHNOGRAPHIC RESEARCH. Research that helps determine patients' and their families' attitudes (i.e., fear, anger, denial, suspicion, skepticism, mistrust) toward their disease, treatments, physicians, social communities, and healthcare systems to which they are attached.

Conducting focus groups, questionnaires, and community surveys will reveal first-hand, real-life cultural and social patterns, knowledge, and awareness that shape the attitudes that will inform effective and pragmatic communications and trial awareness programs necessary to motivate diverse population segments to participate in clinical trials. Ethnographic research will prove to be essential to improve the quality of biomedical research and healthcare delivery with the goal of eliminating racial and ethnic health disparities.

DIVERSITY PLANNING. Translate and integrate research findings into an overall strategic trial plan, including protocol concept and design, recruitment, enrollment, retention, specific trial communications, tools, and tactics.

Clinical trial diversity offers the industry an opportunity to increase its investigator pool of study sites. There is a growing dearth of trained, experienced, and high-performance trial sites. Until companies identify and train new investigators, reflecting diverse populations, it will be difficult to expand the investigator pool and represent inclusion of all populations in clinical trials.

EDUCATION AND TRAINING. Clinical teams and investigative sites need ongoing cross-cultural education and training to ensure successful recruitment and retention of participants.

It is at the clinical trial level that companies must address the "Ghosts of Tuskegee." Companies need to acknowledge that trust deficit issues exist and are a significant factor that prevents optimum inclusion of diverse populations in important studies.

Currently, there is no effective forum for industrywide focus and education of the historical and contemporary evidence of the role of race, ethnicity, language, culture, age, and gender on the health attitudes and behavior of diverse patients and the professionals who treat them.

And there is no forum for industry leaders to analyze best practices in culturally competent outreach to multicultural populations to close the healthcare gap. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com

Trial Advance: The Face of Clinical Trials addresses the fundamental and critical issues of timely clinical trial completion in today's challenging trial environment. For more information, visit trialadvance.com.

Multicultural Healthcare Marketing Group LLC provides integrated, in-language, in-culture healthcare marketing solutions. For more information, visit mhmg-online.com.