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Breast Cancer Trial Enrollment Illustrates Diversity Challenge

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INFOGRAPHIC: Data on industry-sponsored breast cancer studies posted on ClinicalTrials.gov shows how much work remains for drug makers to ensure their studies enroll diverse populations.

A growing number of companies have been publicizing efforts to improve diversity in their clinical trials, highlighting moves like partnerships with community organizations and locating trial sites in areas where they are more likely to recruit racially and ethnically diverse participants. But looking at trial demographics in a particular therapeutic area highlights the scope of the problem they are trying to address, namely the historical tendency to enroll trial populations that are predominantly white and affluent.

Roche Holding AG's Genentech division, for example, has been enlisting trial sites for its inclusive research initiative in the field of oncology. At *The Atlantic's* Health Equity Summit in June, Genentech chief diversity officer Quita Highsmith pointed out that the lack of diversity can undercut research findings, using the example of how artificial intelligence algorithms used for drug discovery in a disease like breast cancer draw their genetic data mostly from white women, meaning those data are not reflective of the general population with what remains the most common type of cancer. (Also see "[Clinical Trial Diversity Efforts Look Beyond COVID-19](#)" - Scrip, 24 Jun, 2021.)

Looking at diversity in breast cancer clinical studies demonstrates how pervasive the issue is in clinical trials overall.

To get a sense of where things stand, *Scrip* combed ClinicalTrials.gov for breast cancer studies with commercial sponsors that began, completed and had data posted on the site between 1 January 2015 and 20 July 2021. Out of 34 Phase I-III studies, 21 included data on participants' race and ethnicity.

The sample chosen is not without limitations. First and foremost, it excludes the hundreds of industry-sponsored breast cancer studies that occurred and completed during that period, but for which data were not posted. And it cannot account for the possibility of errors or omissions in the data that sponsors submitted.

Nevertheless, it provides a snapshot of clinical trial diversity – or rather the lack thereof – in breast cancer studies. Not surprisingly, trials were overwhelmingly white. In most of the trial populations, the percentage of white participants exceeded that of the US population, while Black, Latino and Native Americans were broadly underrepresented. Percentages of Asian enrollees often exceeded that of the US population.

But other things stood out too. In some studies, white participants were a minority. Other studies lacked specific categories for Hispanic/Latino, Native American and in some cases even Asian and Black patients, but grouped significant percentages of participants into categories like “other” and “unknown.”

The trials included sponsors large and small, demonstrating that trial diversity remains an industry-wide problem. But with more and more companies showing a keen and genuine interest in addressing the situation, hopefully the data will show a different picture in the years to come.