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Tufts Center for the Study of Drug Development Establishes Demographic Benchmarks for Pivotal Clinical Trials, Showing Areas of Under-Representation

Disparity of impacts of the coronavirus pandemic underscore need for better demographic representation in trials

BOSTON – May 12, 2020 – Although up to 90% of pivotal clinical trials for drugs approved for sale in the United States provide data on study participants by sex, race, and age, less than four in 10 provide data on ethnicity, according to a newly completed study by the [Tufts Center for the Study of Drug Development](#) that establishes benchmarks for demographic representation.

From 2007 through 2017, participation by women in pivotal Phase III clinical trials fell short of expected participation levels, based on disease prevalence and population census data, the study found; Black and Hispanic/Latinx participants were under-represented and Asians were over-represented.

“Drug developers recognize the importance of participant demographic representation in the development of safe and effective medical treatments,” said Ken Getz, professor and deputy director of Tufts CSDD and principal investigator of the study. “Our study found significant under-representation of participant subgroups in pivotal clinical trials based on population census and disease prevalence.”

The current coronavirus crisis, which in the U.S. has disproportionately affected Black and Hispanic/Latinx populations, highlights the need to ensure demographic representation among clinical study volunteers, especially for medications targeting diseases which may impact different populations differently, Getz said.

The study examined clinical trial and participant demographic data on all 371 new drugs and biologics approved for sale in the U.S. from 2007 through 2017.

Other findings, summarized in the May/June [Tufts CSDD Impact Report](#), released today, include the following:

- Women were under-represented in the studies by 7.3%, while men were over-represented by 7.5%.
- Only 37% of all pivotal trials provided data on study participant ethnicity.
- Blacks or people of African descent were the most under-represented subgroup for trials, with participation rates registering 65% below their levels in general census and disease populations.
- Asian participants were highly over-represented due, in part, to global demographic requirements and classification practices in which an individual's race and/or ethnicity may be categorized differently in different parts of the world.

ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

The Tufts Center for the Study of Drug Development (<http://csdd.tufts.edu>) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the efficiency and productivity of pharmaceutical R&D. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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