National Alliance for Hispanic Health
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National Alliance for Hispanic Health Cautions FDA on 2022 Report on the Risks and Health Benefits of Non-device Software

July 18, 2022. Washington, DC — "The COVID pandemic has changed the acceptance of mHealth throughout the Nation. There is an urgency in FDA's upcoming Congressionally mandated 2022 Report on the risks and health benefits of non-device software to consider the multitude of mHealth software in the new landscape of health and implications of an ongoing lack of adequate data by race, ethnicity, and gender." said Jane L. Delgado, PhD, MS, President and CEO of the National Alliance for Hispanic Health, the Nation's leading Hispanic health advocacy group. In submitting comments for FDA's proposed 2022 report, the Alliance commended FDA for using in the 2020 report the WHO definition of health, i.e., "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity," and urges them to take that definition fully into account as they develop the 2022 Report.

The Alliance called for the 2022 FDA report to recognize the patient safety risk as a result of the lack of inclusion of known differences in drug response by race, ethnicity, and gender (1) and the risk of reliance on clinical decision systems (CDS) that lack adequate race, ethnicity, and gender data from clinical trials. Dr. Delgado added, "Over the past 20 years less than half of clinical trials (43%) in the U.S. reported any race or ethnic data."(2)

1. National Alliance for Hispanic Health. Genes, Culture, and Health: Ensuring the Best Health Outcomes for All. Washington, DC: 20015. https://bit.ly/3ckfWfe
2. Turner, Brandon, Jecca R. Steinberg, Brannon T. Weeks, Fatima Rodriguez, Mark R. Cullen. "Race/ethnicity reporting and representation in US clinical trials: A cohort study." The Lancet Regional Health – Americas. Volume 11, July 2022, 100252. https://doi.org/10.1016/j.lana.2022.100252

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About the National Alliance for Hispanic Health (The Alliance)
The Alliance is the nation's foremost science-based source of information and trusted advocate for the health of Hispanics in the United States with a mission to achieve the best health for all. For more information visit us at www.healthyamericas.org