GSK announces results from 17-year retrospective study on US clinical trial diversity

PUBLISHED FEB 6, 2023
BY GSK

For media and investors only

- Study published today in Clinical Trials: Journal of the Society for Clinical Trials examined clinical trial diversity across 495 GSK trials involving over 100,000 participants

- Results demonstrate real-world disease epidemiology data—compared to the conventional standard of US Census data—may be better benchmark to ensure clinical trial enrolment reflects the populations affected by diseases

- GSK commits to applying insights from the study and collaborating with regulators, patients, academics and other biopharma companies to make meaningful progress on clinical trial diversity

GSK plc (LSE/NYSE: GSK) today announced results from a retrospective study on clinical trial diversity, investigating the historical representation of US-based participants in GSK clinical trials. The study looked at clinical trial demographic data from 495 GSK and ViiV clinical trials involving US-based participants from the period 2002 to 2019. The results published today in Clinical Trials: Journal of the Society of Clinical Trials demonstrate that using real world diseases epidemiology data, rather than the traditional benchmark of US Census Bureau race and ethnicity data, would ensure clinical trial enrolment reflects the populations affected by different diseases.

The results will inform how GSK and potentially other clinical trial sponsors can better design research to represent the diversity of real-world patient populations, given that some diseases disproportionately impact certain racial and ethnic groups. The safety and efficacy of medicines and vaccines can differ based on genetic or environmental factors, and appropriate representation in clinical

research is critical for advancing our understanding of new medicines and vaccines to ensure they have the biggest impact on patients.

Christopher Corsico, Senior Vice President, Development, GSK said: “GSK is committed to ensuring our clinical trials reflect the diverse demographics of the patients impacted by the disease under study, given the disproportional impact some diseases may have on specific patient groups. While we have more to do at GSK, today's publication offers important new data and analyses for sponsors to consider when planning their clinical programmes. To make meaningful progress on diverse participation in clinical trials, we need meaningful collaboration with regulators, patients, academia, other biopharma companies and the wider healthcare ecosystem so that together we can achieve a shared goal of better health outcomes for all.”

US Census Bureau data do not necessarily reflect the proportion of the population by ethnicity that may be impacted by a specific disease. GSK’s study confirmed that in four disease areas (asthma, COPD, HIV and influenza) census data differed from the epidemiological data. For example, while US Census Bureau data indicates 13.4% of the total US population is Black/ African American, 17% of the US population with asthma, 7.1% of those with COPD, 55.3% of those with HIV and 23.7% of those with influenza are Black/African American. In addition, US Census Bureau data indicates 18.5% of the total US population is Hispanic/ Latinx while the proportion of the US population who have each disease who are Hispanic/Latinx is 14.4% for asthma; 6.5% for COPD; 35.7% for HIV and 10.4% for influenza.

The study also showed that GSK trial enrolment for each condition differed by race and ethnicity. For example, enrolment in clinical trials of Black/ African Americans for asthma (22.6%) exceeded both census (13.4%) and epidemiologic (17%) levels. In HIV trials, enrolment of Black/ African Americans at 35.1% markedly exceeded census levels of 13.4% but underrepresented epidemiologic levels of 55.3%.

GSK is committed to applying the insights from the study results in ongoing efforts to improve diversity in clinical trial enrolment. At the end of 2022, 100% of GSK’s Phase III trials had a diversity plan in place to enrol the groups most affected by the disease being studied, as based on epidemiology data. GSK is working with patient advocacy groups and academic organisations to tackle the barriers that negatively impact clinical trial turnout of certain patient populations,

such as access to transportation, language differences, lack of trust and awareness. One way GSK is addressing these barriers is by rolling out global cultural competency training to around 15,000 clinical trial staff members so they can engage with diverse communities and advocacy groups to build trust, enhance disease awareness and provide appropriately tailored information.

Further research will support industry efforts to improve representation in clinical trials. To build on the US-focused analysis published today, GSK is currently evaluating retrospective clinical trial demographic data for past participants who were enrolled in other countries around the world. Regional, demographic and therapeutic area analyses of the full global data set are planned to further expand on the evidence base for improving diversity benchmarking in future clinical research.

The study (

> Demographic diversity of US-based participants in GSK-sponsored interventional clinical trials

) included analysis of GSK-sponsored interventional phase I to IV clinical trials conducted from 2002 to 2019 across three areas: pharmaceutical (which includes therapeutic medicines except for vaccines and HIV therapies); vaccine (which includes both prophylactic and therapeutic vaccines); and ViiV (which includes HIV therapies). A total of 1005 global trials were identified, of which 495 had US-based sites with a total of 108,261 US participants (pharmaceutical, n=357 trials; vaccine, n=45 trials; ViiV, n=93 trials). Further details can be found in the Clinical Trials: Journal of the Society for Clinical Trials.

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com/company

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's

Annual Report on Form 20-F for 2021, GSK's Q4 Results for 2022 and any impacts of the COVID-19 pandemic.

Press release distributed by Wire Association on behalf of GSK, on Feb 6, 2023. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/gsk-announces-results-from-17-year-retrospective-study-on-us-clinical-trial-diversity-1782

GSK

Newsroom: https://wireassociation.eu/newsroom/gsk
Website: https://www.gsk.com/
Primary Email: corporate.media@gsk.com

Social Media

Facebook - https://www.facebook.com/GSK
Twitter - http://twitter.com/GSK
Youtube - http://www.youtube.com/GSK
Linkedin - http://www.linkedin.com/company/glaxosmithkline
Instagram - https://www.instagram.com/gsk/
