

THE IMPORTANCE OF BYOD IN WOMEN'S HEALTH STUDIES

EXECUTIVE BRIEF

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The number of electronic devices in use globally was approximately 6.2 billion in 2021 and is expected to reach 6.4 billion in 2022 (Goasduff, 2021). Like other industries, healthcare is undergoing a transition from traditional paper formats to digital tools. This transition ranges from physical devices, such as computers, tablets, and mobile phones, to various software applications and wearable devices.

Having experienced the freedom of choosing one's own device across both personal and professional life, end users have developed an expectation to be able to "bring your own devices" (BYOD) in healthcare as well. A national survey reported that over half --58.23% -- of mobile phone users have downloaded at least one health-related mobile app in the past (Krebs & Duncan, 2015). The COVID-19 pandemic has only accelerated this trend toward BYOD in healthcare.

For organizations and employees, BYOD helps to reduce expenses, increase productivity, and improve communication and workflows through automation (Williams, 2014). For patients, the digitization of data collection and the option of BYOD at home alleviates both the physical (e.g., traveling), and financial (e.g., day-off without pay) burdens of commuting between healthcare facilities and their homes. Further, BYOD improves usability and user experiences by making the most of digital platforms. High compliance and engagement constitutes an important advantage of BYOD. In a conference abstract, Khurana et al. (2021) reported an average compliance rate of 89% after reviewing 15 BYOD clinical trials that collected electronic Clinical Outcome Assessment (eCOA) data across various therapeutic areas (e.g., CNS, hematology, dermatology, pulmonology, women's health, and

virology). In addition, BYOD was correlated with higher engagement in comparison to study-provided devices in terms of both frequency and duration of application usage (Pugliese et al., 2016). Consistent with this literature, Datacubed Health's mobile application has been found to contribute to robust and resilient compliance. In a 55-day clinical study involving daily

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completion of electronic patient-reported outcomes (ePROs) through Datacubed's app, 93.5% of participants were retained until study end. The compliance rate for these retained participants was 100% ("Virtual Trials", 2021). In a longer study which utilized the app for 6 months, a retention rate of 87% was obtained at study completion, with 95% compliance among those retained (Bayer & Glimcher, 2019).

Women's Health in Clinical Trials

Historically, clinical trial research in the U.S. has mainly relied on young adult male participants. The exclusion of female participants has been driven by various factors, such as the perception that data from males are easier to analyze than data from females, because of estrus and/or menstrual cycles, and concerns over potential negative impacts of medications and/or treatments on fetuses in pregnant participants (Killien et al., 2000). This exclusion stands in stark contrast to the health disparities faced by women in the U.S., especially compared to men and women in other high-income countries. For example, in comparison to men, women have higher rates of vision abnormalities (e.g., hyperopia, myopia, glaucoma, etc.; Clayton & Davis, 2015), a greater share of adult obesity (Hales et al., 2018), and lower liver transplant rates (Mathur et al., 2011).

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Other factors, ranging from molecular and physiological sex differences to societal and cultural beliefs and practices, have further contributed to these gender-based health disparities. For example, an international analysis of breast cancer incidence found higher incidence rates and increasing trends in female breast cancer compared to males, with the highest rates being observed in the U.S. (Ly et al., 2013). Other research has shown that women experience health disparities due to sociocultural biases (e.g., healthcare provider behaviors), such as lower liver transplant rates and a greater likelihood to remain on the transplant waiting list (Mathur et al., 2011). Even more troubling is that this inequality is most prevalent in women with higher mortality risks (Mathur et al., 2011). Many other disparities between women and men, such as the incidence of vision abnormalities (Clayton & Davis, 2015)

and lung disease (Pinkerton et al., 2015), are the result of a combination of biological and sociocultural biases.

No matter the reasons driving the health disparities impacting women, increased inclusion of women in clinical trials is critical for improving research outcomes. A more inclusive environment will enable more objective examinations of biological and sociocultural factors and their implications for clinical treatments and practices. Extrapolating treatments, medications, and practices based on male-dominant data puts women and other groups at unnecessary risk and must be avoided.

BYOD and Women's Health

To advance the health of women, researchers must move beyond compartmentalized and antiquated notions of biological sex. Women are not a homogenous group of individuals. Gender, gender identity, age, socioeconomic status, education, cultural background, geographical location, disability status, and numerous other factors have a bearing on the health of any population. Killien and colleagues (2000) highlight several key challenges faced by historically marginalized and underrepresented women in clinical trial research. These include lack of child or family care options, transportation limitations, scheduling conflicts, and a lack of knowledge and/or trust. BYOD is uniquely positioned to address a number of these concerns.

With BYOD, participants are already familiar with the device they use for a clinical trial, improving accessibility and usability. In addition, participants can complete certain study activities without having to schedule in-person visits, saving time and resources for the participant, site, and sponsor. High compliance and engagement are further benefits of the BYOD approach. The collective advantages of BYOD are further strengthened when supported by the Datacubed Health platform. Specifically, with features such as eConsent and Virtual Visit, Datacubed reduces potential sources of friction for participation (e.g., scheduling conflicts, time spent commuting, cost of transportation, lost wages due to missed work). Datacubed's mobile app supports automated reminders and notifications and can be used to share information which keeps participants engaged and informed, fostering trust. The

app also provides opportunities to nurture a sense of personal connection through identity lock, a behavioral science approach that connects a participant's identity to participation in the study, reinforcing the participant's role as a partner and scientific contributor to the study, rather than simply being a study subject. Further, Datacubed Health's integration capabilities with sensors and wearables allow researchers to collect real-world data, passively, to gain insight into individual characteristics such as physical activity levels, heart rate, and social and behavioral patterns, all without placing additional burdens on participants.

Conclusion

The literature is clear: gender bias in clinical trial research has contributed to gender-based health disparities. This fact has also been recognized by

government agencies such as the United States Food and Drug Administration (FDA; U.S. Department of Health and Human Services et al., 2020) and the National Institutes of Health (NIH; National Institutes of Health, 2019). The BYOD model can alleviate some common impediments women face in clinical trials and facilitate the improvement of women's health and wellbeing.

Datacubed Health's platform fully supports BYOD and is further strengthened by behavioral science to offer greater accessibility, affordability, trust, and usability to all genders in clinical trials. By leveraging Datacubed Health's BYOD approach, researchers can expect higher compliance and retention in addition to more accurate data capture, allowing for improved analysis of population-specific factors.

References

- Bayer, H., & Glimcher, P. W. (2019). PNS250 USING TOOLS OF BEHAVIORAL SCIENCE TO IMPROVE PATIENT ENGAGEMENT, RETENTION AND ADHERENCE. *Value in Health*, 22, S328–S329. <https://doi.org/10.1016/j.jval.2019.04.1605>
- Clayton, J. A., & Davis, A. F. (2015). Sex/Gender Disparities and Women's Eye Health. *Current Eye Research*, 40(2), 102–109. <https://doi.org/10.3109/02713683.2014.986333>
- Goasduff, L. (2021). *Gartner forecasts global devices installed base to reach 6.2 billion units in 2021*. Gartner. Retrieved February 9, 2022, from <https://www.gartner.com/en/newsroom/press-releases/2021-04-01-gartner-forecasts-global-devices-installed-base-to-reach-6-2-billion-units-in-2021>
- Hales, C. M., Fryar, C. D., Carroll, M. D., Freedman, D. S., & Ogden, C. L. (2018). Trends in Obesity and Severe Obesity Prevalence in US Youth and Adults by Sex and Age, 2007–2008 to 2015–2016. *JAMA*, 319(16), 1723–1725. <https://doi.org/10.1001/jama.2018.3060>
- Khurana, L., Reed, D. L., Hutchin, J., Lima, V., Arnera, V., & Cascade, E. (2021). PMU61 State of BYOD: Lessons in Acceptability and Compliance from 35 Trials. *Value in Health*, 24, S155. <https://doi.org/10.1016/j.jval.2021.04.773>
- Killien, M., Bigby, J. A., Champion, V., Fernandez-Repollet, E., Jackson, R. D., Kagawa-Singer, M., Kidd, K., Naughton, M. J., & Prout, M. (2000). Involving Minority and Underrepresented Women in Clinical Trials: The National Centers of Excellence in Women's Health. *Journal of Women's Health & Gender-Based Medicine*, 9(10), 1061–1070. <https://doi.org/10.1089/152460900445974>
- Krebs, P., & Duncan, D. T. (2015). Health App Use Among US Mobile Phone Owners: A National Survey. *JMIR MHealth and UHealth*, 3(4), e101. <https://doi.org/10.2196/mhealth.4924>
- Ly, D., Forman, D., Ferlay, J., Brinton, L. A., & Cook, M. B. (2013). An international comparison of male and female breast cancer incidence rates. *International Journal of Cancer*, 132(8), 1918–1926. <https://doi.org/10.1002/ijc.27841>
- Mathur, A. K., Schaubel, D. E., Gong, Q., Guidinger, M. K., & Merion, R. M. (2011). Sex-Based Disparities in Liver Transplant Rates in the United States. *American Journal of Transplantation*, 11(7), 1435–1443. <https://doi.org/10.1111/j.1600-6143.2011.03498.x>
- National Institutes of Health. (2019). *Advancing Science for the Health of Women: The Trans-NIH Strategic Plan for Women's Health Research*. https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH_Strategic_Plan_2019_02_21_19_V2_508C.pdf

Pinkerton, K. E., Harbaugh, M., Han, M. L. K., le Saux, C. J., van Winkle, L. S., Martin, W. J., Kosgei, R. J., Carter, E. J., Sitkin, N., Smiley-Jewell, S. M., & George, M. (2015). Women and lung disease: Sex differences and global health disparities. *American Journal of Respiratory and Critical Care Medicine*, 192(1), 11–16. <https://doi.org/10.1164/rccm.201409-1740PP>

Pugliese, L., Crowley, O., Woodriff, M., Lam, V., Sohn, J., & Bradley, S. (2016). Feasibility of the “Bring Your Own Device” Model in Clinical Research: Results from a Randomized Controlled Pilot Study of a Mobile Patient Engagement Tool. *Cureus*. <https://doi.org/10.7759/cureus.535>

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), & Center for Biologics Evaluation and Research (CBER). (2020). *Enhancing the Diversity of Clinical Trial Populations-Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry*. <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugsand/or-virtual-trials-yields-high-patient-compliance-with-datacubed/>

Williams, J. (2014). Left to Their Own Devices How Healthcare Organizations Are Tackling the BYOD Trend. *Biomedical Instrumentation & Technology*, 48(5), 327–339. <https://doi.org/10.2345/0899-8205-48.5.327>

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