

Sex as a Biological Variable

Biological differences may contribute to variations in the safety and efficacy of medical products



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Understanding sex differences at FDA

Research has shown that biological differences between men and women (differences due to sex chromosome or sex hormones) may contribute to variations seen in the safety and efficacy of drugs, biologics, and medical devices. FDA's regulations and guidance acknowledge that understanding mechanisms of sex differences in medical product development is crucial for regulatory decisions and optimal treatment outcomes.

FDA's Office of Women's Health (OWH) advocates for the participation of [women in clinical trials](#) ([/consumers/womens-health-topics/women-clinical-trials](#)), supports scientific sex differences [research](#) ([/consumers/womens-health/womens-health-research](#)) within and outside FDA, and provides sex differences [training](#) ([/consumers/womens-health/owh-education-and-training](#)) and other [resources](#) ([/consumers/womens-health/owh-resources-stakeholders](#)) for health professionals.

Women in clinical trials

OWH was [established \(/consumers/about-owh/owh-historical-information\)](/consumers/about-owh/owh-historical-information) in 1994 to advocate for the participation of women in clinical trials and the analyses of data by sex. OWH supports studies to track the participation of women in clinical trials and collaborates with FDA's centers and external partners to conduct trainings, workshops, outreach, and research to improve clinical trials design, recruitment, and analyses and to support FDA regulatory policy and decision-making.

Information in this section is provided for historical context, and should not be considered the most current information. For current information, see [Women in Clinical Trials \(/consumers/womens-health-topics/women-clinical-trials\)](/consumers/womens-health-topics/women-clinical-trials), [Women's Health Research \(/consumers/womens-health/womens-health-research\)](/consumers/womens-health/womens-health-research), [News and Updates \(/consumers/womens-health/owh-news-and-updates\)](/consumers/womens-health/owh-news-and-updates), and [Education and Training \(/consumers/womens-health/owh-education-and-training\)](/consumers/womens-health/owh-education-and-training) from OWH.

Related links

- [About OWH Research \(/consumers/womens-health-research/about-owh-research\)](/consumers/womens-health-research/about-owh-research)
- [Women's Health Research Roadmap \(/consumers/about-owh-research/womens-health-research-roadmap\)](/consumers/about-owh-research/womens-health-research-roadmap)