Women in Clinical Trials: FDA Perspective

CTTI Meeting
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Disclaimer

The views expressed are those of the speaker and do not necessarily reflect official policy of the US FDA. No official endorsement by the US FDA is intended or should be inferred.
Our Mission

- **Promote the inclusion of women in clinical trials** and the implementation of guidelines concerning the representation of women in clinical trials and the completion of data analysis.

- **Identify and monitor the progress of crosscutting and multidisciplinary women’s health initiatives** including changing needs, areas that require study, and new challenges to the health of women as they relate to FDA’s mission.

- **Serve as the principal advisor** to the Commissioner and other key Agency officials on **scientific, ethical, and policy issues** relating to women's health.

Office of Women’s Health
OWH achieves its mission through the foundational principle that Sex is a Biological Variable (SABV)
2015-2019
DRUG TRIALS SNAPSHOTs
SUMMARY REPORT
Five-Year Summary and Analysis of Clinical Trial Participation and Demographics

Global - 51% Female
US - 56% Female
Participation of Women in Clinical Trials Supporting FDA Approval of Cardiovascular Drugs

Pamela E. Scott, PhD, MA; Kita P. Uting, MD; Marjorie R. Jenkins, MD, MEdBiP; Mary Ross Southworth, MD; Tan Yen McGrewell, PhD; Ruth J. Geller, MBBS; Monica Katz, HS; Robert J. Temple, MD; Janet Woodcock, MD
Texas Women in Clinical Trials = HOPE

Clinical trials are research studies that help to show whether a test or treatment works and is safe. There are many ways you can take part in a trial. Some trials ask you questions about treatments you already take. In other trials, you take a new drug. Some clinical trials use healthy people. Others use people who have a specific health problem.

Ask your healthcare provider if a clinical trial is right for you.

Are Women in Clinical Trials?
Yes. Women are already in clinical trials. However, women from diverse backgrounds still need to participate. Women of all ages, racial and ethnic groups, and women with disabilities or chronic health conditions should think about being in a clinical trial.

You can help by considering a trial for yourself. You can make a difference by helping doctors learn more about women's health.

Why Should Women Participate?
Medical products can affect men and women differently. It is important that women participate because women sometimes have different side effects. A woman's body can also affect how drugs and devices work.

FDA Office of Women's Health
www.fda.gov/womeninclinicaltrials

Office of Women's Health
FDA Guidance for Industry

Representatives of both sexes should be included in clinical trials in numbers adequate to allow detection of clinically significant sex-related differences in drug response.
OWH created the first FDA Women’s Health Research Roadmap

1. Advance Safety and Efficacy
2. Improve Clinical Study Design and Analysis
3. Evaluate New Modeling and Simulation Approaches
4. Advance Biomarker Science
5. Expand Data Sources and Analysis
6. Improve Health Communications
7. Identify Sex Differences via Emerging Technologies

Priority Areas Outlined in OWH Women’s Health Research Roadmap

Read the Women’s Health Research Roadmap
https://www.fda.gov/science-research/womens-health-research/womens-health-research-roadmap

Office of Women’s Health
Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)
The 21st Century Cures Act P.L. 114-255

- Advise the Secretary of Health and Human Services (HHS) regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women
- OWH serves as the FDA lead to the Task Force
- 15 recommendations
- Implementation of recommendations report – Summer 2020


Office of Women’s Health
FDA Office of Women’s Health
Pregnancy Registries Webpage

www.fda.gov/pregnancyregistries

- Connects pregnant women and health professionals to ~123 registries
- Links to drug information
- Patient education resources
- www.fda.gov/pregnancyregistries

Office of Women’s Health
Visit: https://cure.ncats.io/

Office of Women’s Health
Available NOW: Free Online Courses Addressing Sex and Gender

Developed by the NIH Office of Research on Women’s Health in partnership with the FDA Office of Women’s Health

Bench to Bedside: Integrating Sex and Gender to Improve Human Health
Explore sex- and gender-related differences in human health and disease.

Register at https://go.usa.gov/xvGwn.
Recent OWH Publications

Evaluation of worldwide clinical trials by gender: An FDA perspective

US Food and Drug Administration Office of Women's Health: Promoting Therapeutic Optimization in Women

Progress and opportunities for women in clinical trials: A look at recent data and initiatives from the U.S. FDA

Stay Connected with FDA OWH

SIGN UP FOR A PREGNANCY REGISTRY

You can make a difference in #WomensHealth. Women of all ages, racial & ethnic groups, and women with disabilities or chronic health conditions are needed for clinical trials. Ask your healthcare provider if a #ClinicalTrial is right for you. fda.gov/womeninclinical...

Diversity in clinical trials is key for understanding the health of all women. Women of all ages, races, and ethnicities and women with disabilities or chronic health conditions can participate.

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Thank you

www.fda.gov/womens
www.fda.gov/womenshealthresearch
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