



**U.S. FOOD & DRUG**  
ADMINISTRATION

Office of Women's Health

# FDA Broad Agency Announcement (BAA) Day

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# Office of Women's Health: Mission

FDA

- 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 appropriate data analysis
- Identify and monitor the progress of crosscutting and multidisciplinary women's health initiatives
- Provide guidance on scientific, ethical, and policy issues relating to the health of women
- Advance research that facilitates regulatory decision-making and the understanding of sex differences and health conditions unique and disproportionate to women



# Sex as a Biological Variable

## Sex Matters in Biomedical Research

*Females and males are not the same*

- ✓ Hormonal and anatomical differences
- ✓ Differences in safety and efficacy
- ✓ Differences in drug metabolism
- ✓ Differences in susceptibility to disease

### Infectious Diseases

*Sex differences in susceptibility to various infectious agents*

### Autoimmune Diseases

*Females show increased susceptibility*

### Cancers

*Males show increased susceptibility to non-reproductive malignancies*

*Sex should be considered at all levels of research: cellular, animal, and human studies*



# OWH Research Priority Areas

Advance Safety and Efficacy

Improve Health Communications

Improve Clinical Study and Design Analysis

Combat Emerging Health Threats

Promote Emerging Technologies And Methodologies

Advance Biomarker Science

Expand Data Sources and Analysis



# FY26 Topics of Particular Interest



## Menopause

Symptoms, treatments, hormone therapy, and long-term health impacts.



## Adverse Events

Sex differences in drug safety, pharmacogenomics in women, including adverse events, genetic risk factors for drug toxicity, and drug-drug interactions.



## Chronic Diseases

Cardiovascular, autoimmune, oncology, and other conditions affecting women.



## Nutrition

Dietary supplements, nutritional needs across lifespan, and food safety.



# FY26 Topics of Particular Interest



## Cosmetics and Dyes

Safety, adverse reactions, and regulatory considerations for cosmetic products



## Microbiome

Women's health implications, therapeutic applications, and regulatory science

## Emerging Methods

*We seek projects using AI, machine learning, and other innovative approaches for women's health research.*

**Do not feel limited by these topics- we welcome innovative proposals.**

# What We're Looking For

## Project Characteristics

- ✓ Key women's health issues - particularly those with limited recent funding
- ✓ Align with OWH Research Roadmap priorities
- ✓ Crosscutting and multidisciplinary approaches
- ✓ Thread across FDA Centers
- ✓ Very clear regulatory impact

***We fund a variety of projects including social/behavioral science, bench science, and clinical research***

# Contact & Resources



## OWH Women's Health Research Roadmap

Available on the OWH Website

*Strategic direction for women's health research at FDA*

FDA Office of Women's Health

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