



FDA OFFICE OF WOMEN'S HEALTH

FDA Broad Agency Announcement: FY25 BAA DAY

Speaker: Joyce Obidi, PhD



November 4, 2024

Office of Women's Health: **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 appropriate data analysis
- **Identify and monitor the progress of crosscutting and multidisciplinary women's health initiatives**
- **Serve as the principal advisor** to the Commissioner and other key Agency officials on **scientific, ethical, and policy issues** relating to the health of women

Sex ≠ Gender

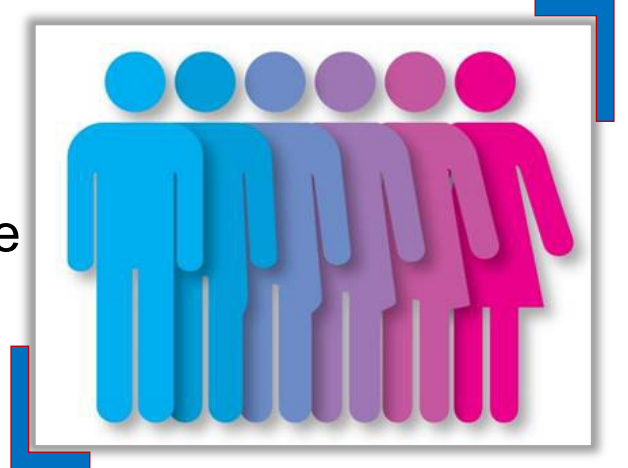
SEX is a BIOLOGICAL VARIABLE



- Chromosomal
- Physiological
- Typically, binary
 - Male/Female

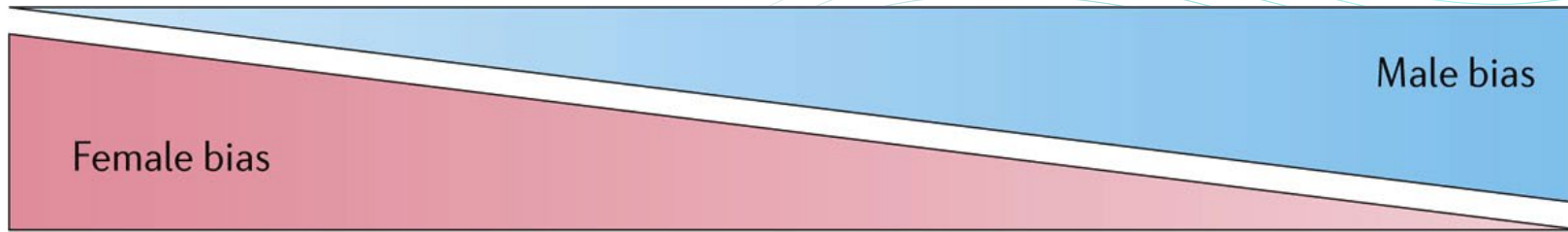
GENDER is a SOCIAL CONSTRUCT

- Environmental
- Society
- Spectrum
 - Masculine/Feminine
 - Man/Woman
 - Both
 - Neither



Source: (2001) [Exploring the Biological Contributions to Human Health: Does Sex Matter](#)

Sex bias in infectious diseases, inflammatory diseases, and cancers



Autoimmune diseases	Infectious diseases	Non-reproductive cancers	
<ul style="list-style-type: none">• Graves disease• Hashimoto thyroiditis• Multiple sclerosis• Rheumatoid arthritis• Systemic lupus erythematosus• Type 1 diabetes	<ul style="list-style-type: none">• HIV• Influenza• Toxoplasmosis• Legionella• Malaria• Zika	<ul style="list-style-type: none">• Ebola• MERS• Hepatitis B• Tuberculosis• Leptospirosis• Campylobacter• Schistosomiasis• Amebiasis• Aspergillosis	<ul style="list-style-type: none">• Bladder• Bowel• Kidney• Leukaemia• Liver• Lung• Malignant melanoma• Oesophagus• Stomach

Nature Reviews | Immunology



FDA Office of the Commissioner



OFFICE OF WOMEN'S HEALTH

Working Across FDA to Progress Women's Health

Research/Funding Policy Development Professional Training Consumer Information



Center for
Drug
Evaluation
and Research

Center for
Devices and
Radiologic
Health

Center for
Biologics
Evaluation
and Research

Human Foods
Program

National
Center
for Toxicology
Research





OWH Scientific Programs

**Intramural
Research**
(OCS annual process)

**Special Funding
Projects**
(submitted throughout the
year)

**Extramural
Research**
(CERSI, BAA)

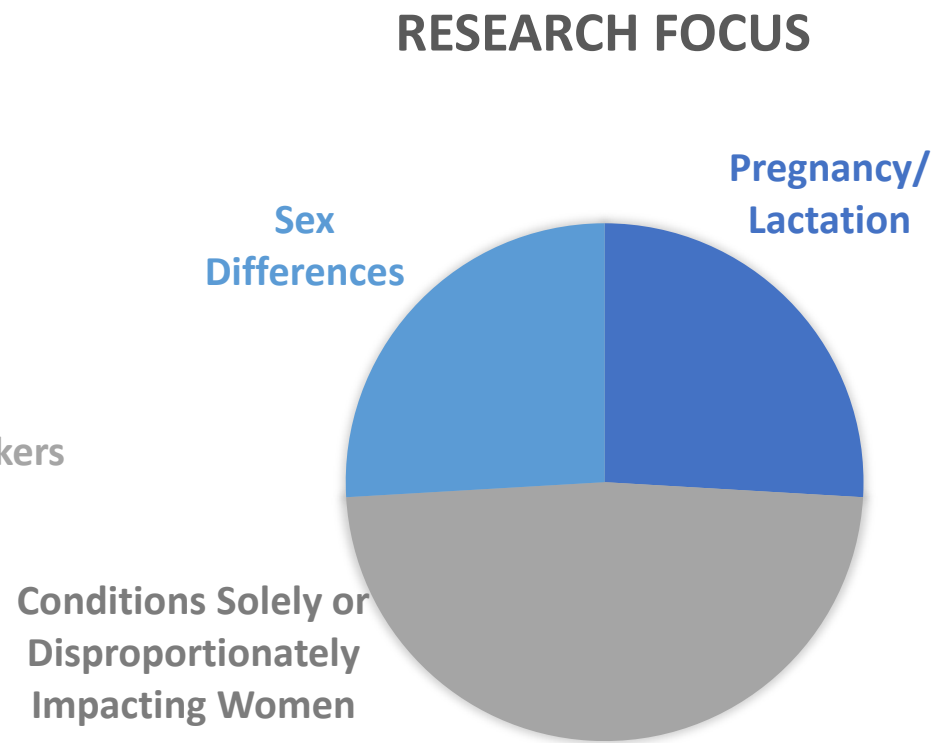
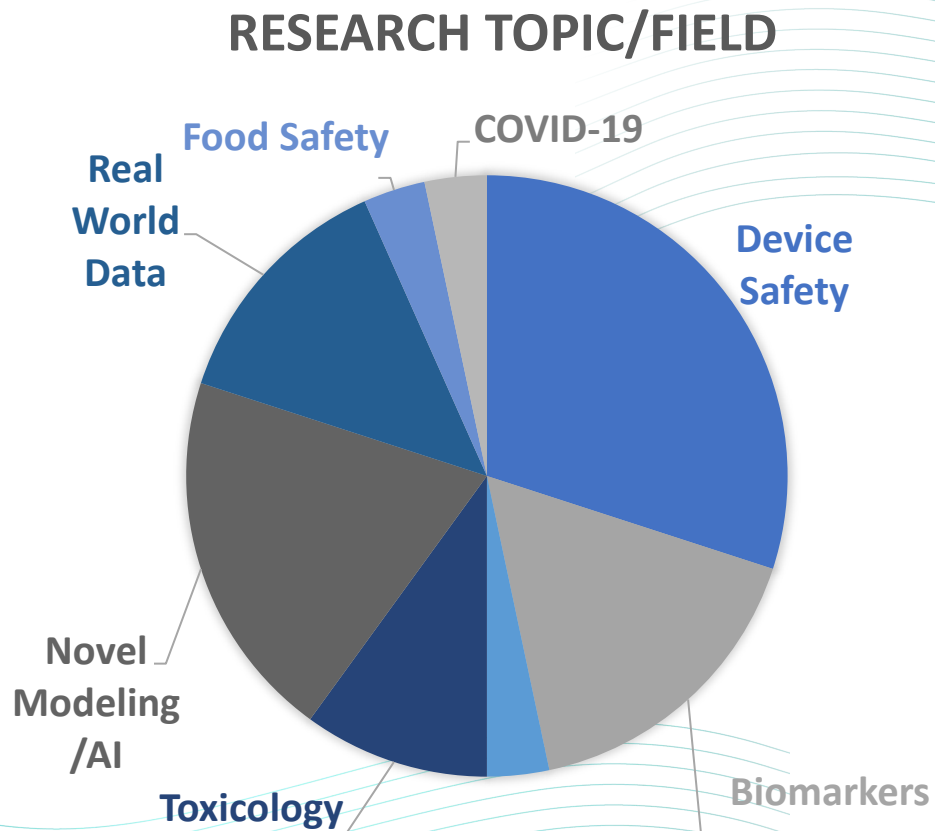
**OWH Staff
Fellowship**

**Scientific Speaker
Series**

**Public Meetings/
Workshops**



Snapshot of Intramural Research Projects Funded by OWH FY2019-2024



Previous OWH Funded BAA's



- WebMD: **Understanding Safe Medication Use by Women's Health Special Populations**
- WebMD: **Women's Perspectives of Lupus Clinical Research Participation**
- Husson University/SUNY Binghamton University: **Predicting the Transfer of Breast Cancer Resistant Protein (BCRP) Substrates into Human Milk Using *In Vitro* to *In Vivo* Extrapolation (IVIVE)**





Improved
Product
Safety

Improved Regulatory
Decision-Making

Advancing
Women's Health and
Public Health





PRIORITY AREAS

6. Promote Emerging Technologies and Methodologies

2. Improve Clinical Study Design and Analyses

5. Improve Health Communications

4. Expand Data Sources and Analysis

1. Advance Safety and Effectiveness

3. Advance Biomarker Science

7. Combat Emerging Health Threats

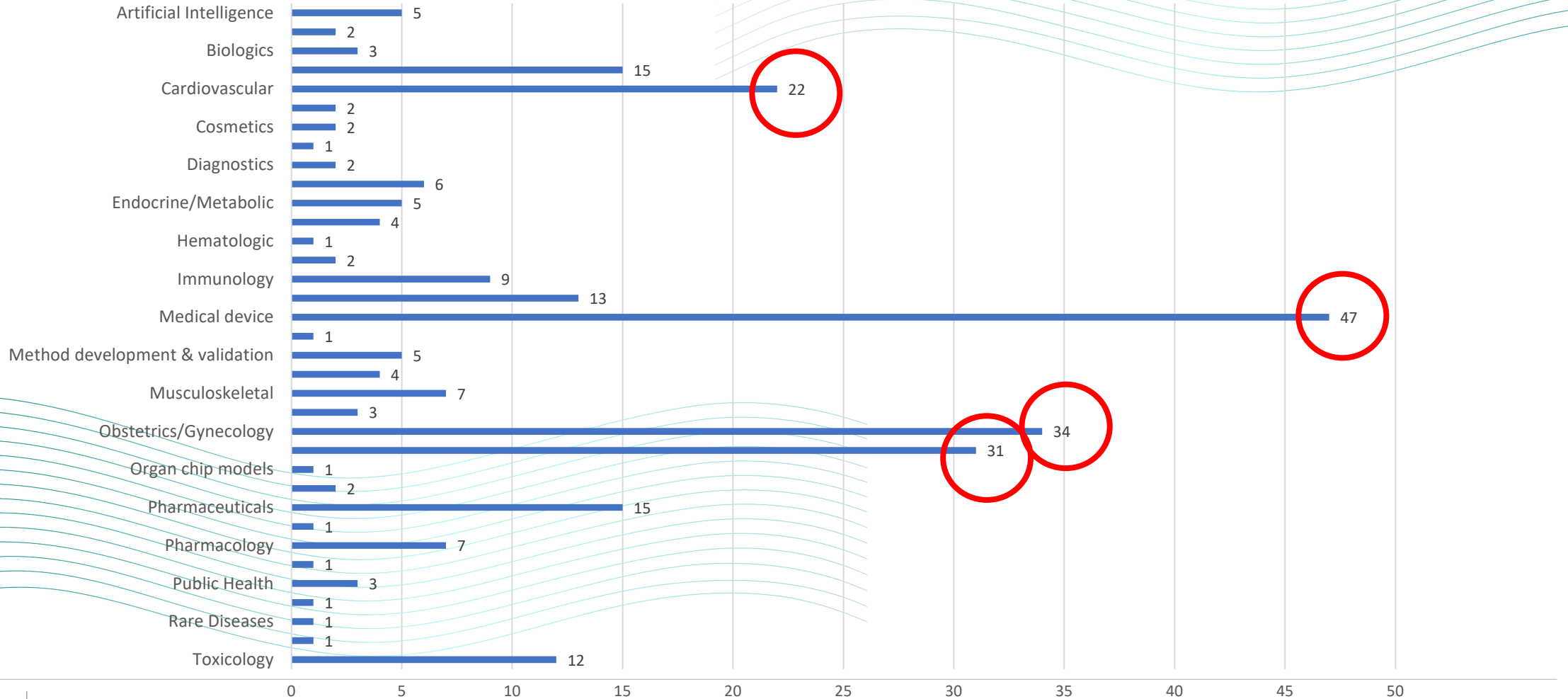
Read the Women's Health Research Roadmap:
<https://www.fda.gov/science-research/womens-health-research/womens-health-research-roadmap>



OWH Research Areas (FY12-FY23)



Project Tags



Opportunities for OWH Funding



- **OWH consider projects which:**
 - Involve key women's health issues
 - Align with the OWH Research Roadmap priorities
 - Include crosscutting and multidisciplinary women's health priority areas important to the Agency and thread across the Centers

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Thank you

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 @FDAWOMEN



FY25 Research Priority Topics



Novel treatments for conditions disproportionately affecting women

Addressing knowledge gaps in the leading causes of death in women

Safety of cosmetics, colors, dietary supplements, and cannabis-derived products

Sex and gender considerations for diagnostics, treatments, and prevention of emerging public health concerns

Pharmacogenomics in women, including genetic risk factors for drug toxicity

Incorporating patient input and RWD into regulatory decision-making

Use of real-world data and evidence to inform regulatory processes

Innovative strategies to engage and enroll women in clinical trials

Safety and efficacy in pregnant people, lactating people, or older women

