



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

Office of Women's Health

FDA Broad Agency Announcement (BAA) Day

Joyce Obidi, PhD
October 25, 2023



Office of Women's Health: Mission

FDA

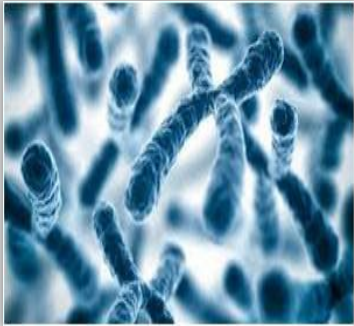


- **Promote the inclusion of women in clinical trials** and the implementation of guidelines concerning the representation of women in clinical trials and the completion of appropriate data analysis
- **Identify and monitor the progress of crosscutting and multidisciplinary women's health initiatives**
- **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



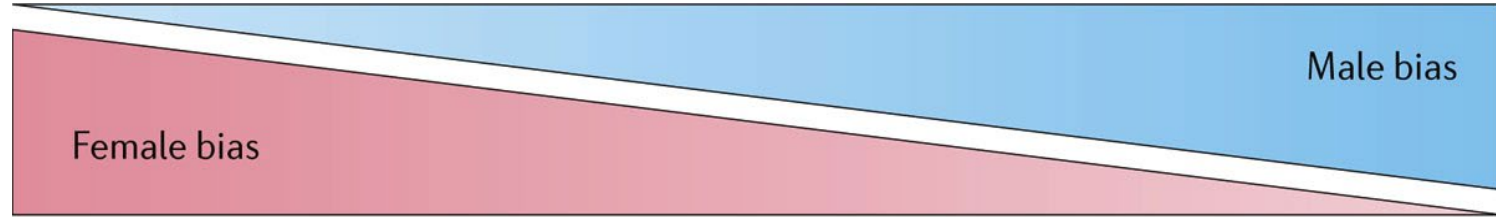
- Chromosomal
- Physiological
- Typically, binary
 - Male/Female

GENDER is a SOCIAL CONSTRUCT

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



Sex bias in infectious diseases, inflammatory diseases, and cancers



Autoimmune diseases

- Graves disease
- Hashimoto thyroiditis
- Multiple sclerosis
- Rheumatoid arthritis
- Systemic lupus erythematosus
- Type 1 diabetes

Infectious diseases

- HIV
- Influenza
- Toxoplasmosis
- Legionella
- Malaria
- Zika
- Ebola
- MERS
- Hepatitis B
- Tuberculosis
- Leptospirosis
- Campylobacter
- Schistosomiasis
- Amebiasis
- Aspergillosis

Non-reproductive cancers

- Bladder
- Bowel
- Kidney
- Leukaemia
- Liver
- Lung
- Malignant melanoma
- Oesophagus
- Stomach





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

Center for
Food
Safety
and
Nutrition

National
Center
for
Toxicology
Research



OWH Scientific Programs

Intramural Research Grants
(OCS annual process)

Special Funding Projects
(submitted throughout the year)

External Research
(CERSI, BAA)

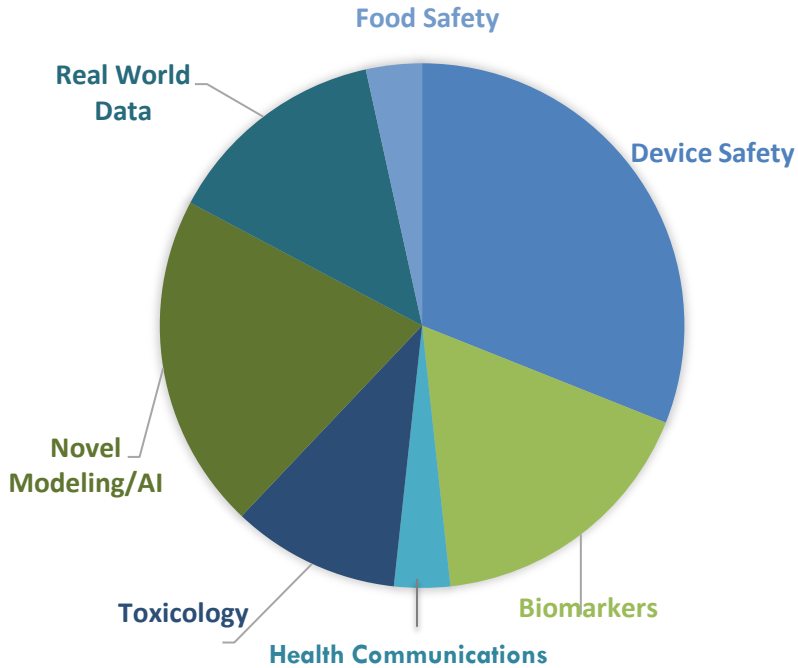
Women's Health Research Fellowship

Scientific Speaker Series

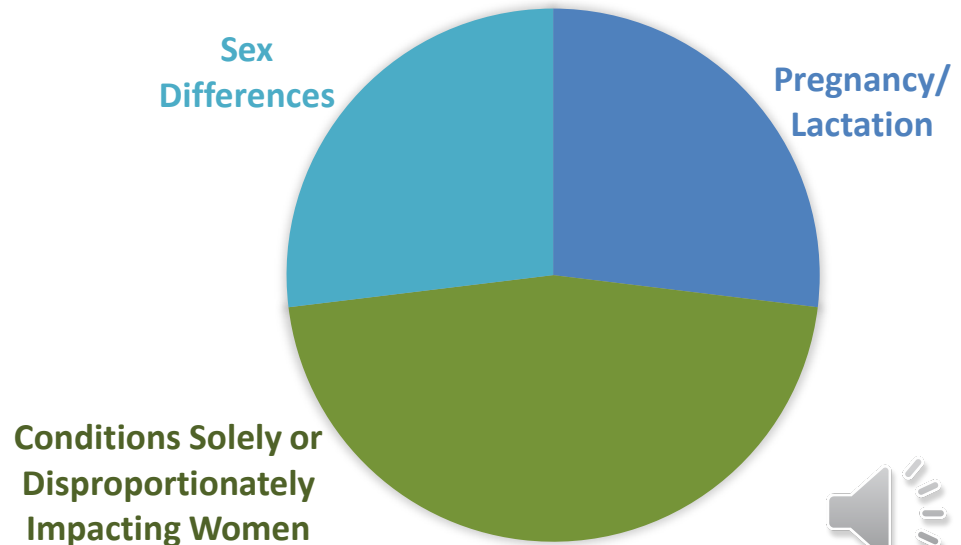
Public Meetings/ Workshops

Snapshot of Intramural Research Projects Funded by OWH FY2019- 2022

RESEARCH TOPIC



RESEARCH FOCUS

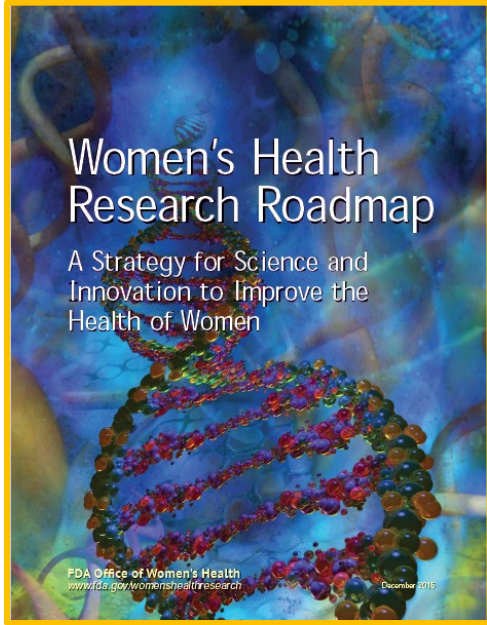




Previous OWH Funded BAA's

- 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



RESEARCH ROADMAP

Women's Health Research Roadmap



Priority Areas

1. Advance Safety and Efficacy

2. Improve Clinical Study and Design Analysis

3. Evaluate New Modeling and Simulation Approaches

4. Advance Biomarker Science

5. Expand Data Sources and Analysis

6. Improve Health Communications

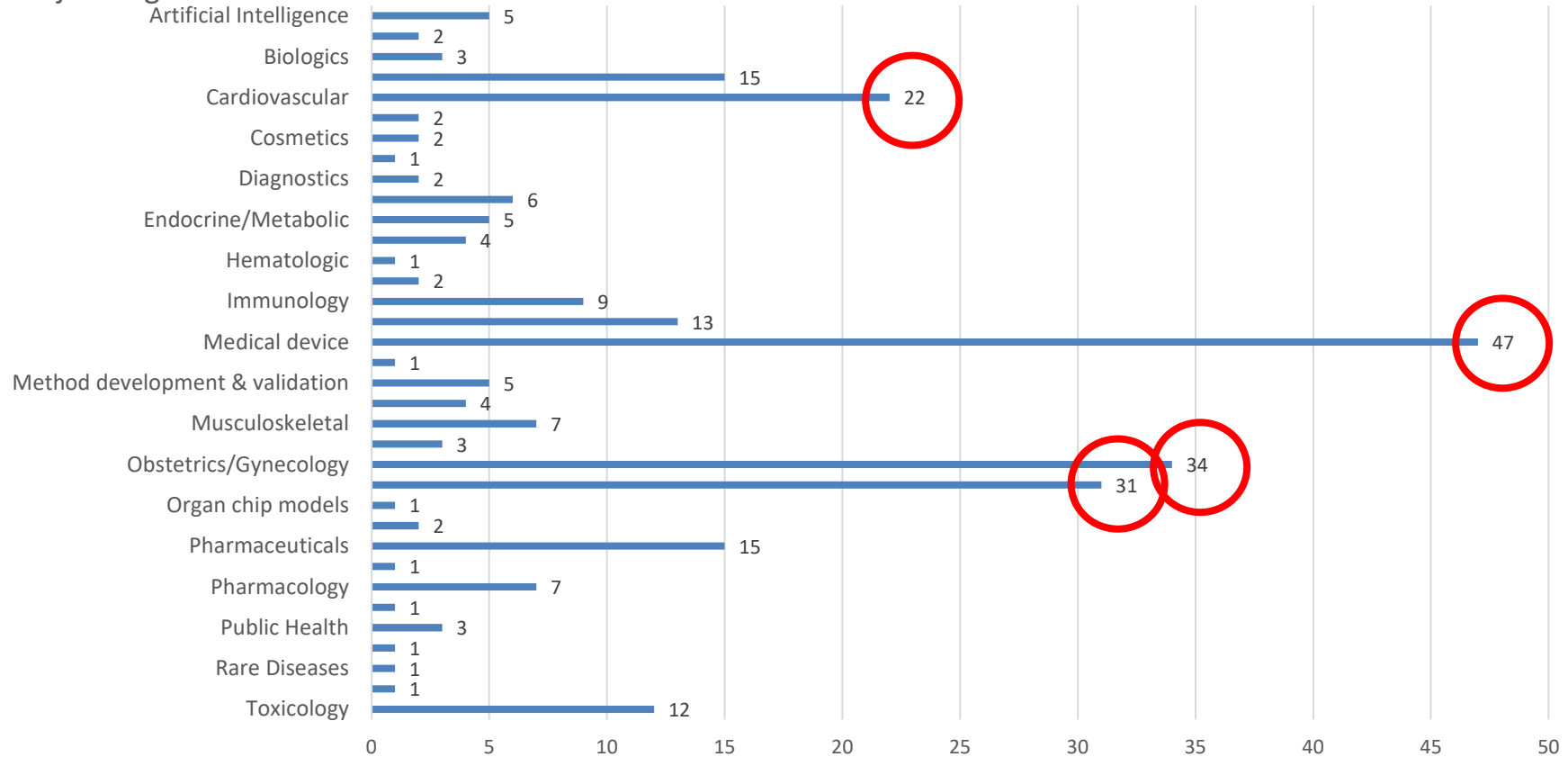
7. Identify Sex Differences via Emerging Technologies



OWH Research Areas (FY13-FY23)



Project Tags



FY24 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



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

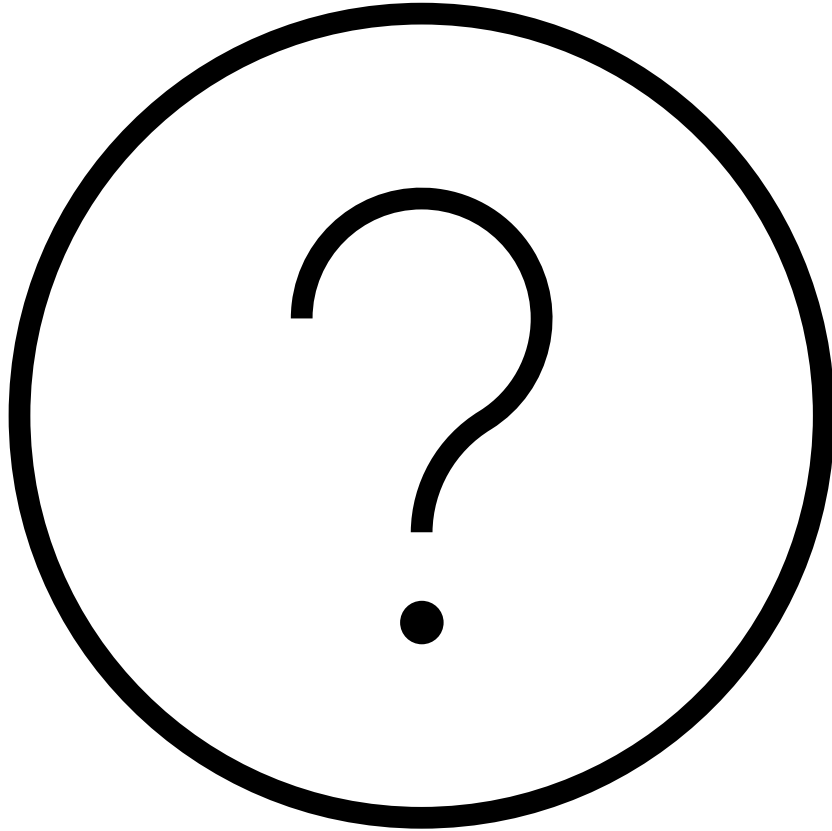


Contact Us



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