



FDA Broad Agency Announcement (BAA) Day

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FDA OFFICE OF WOMEN'S HEALTH
December 6, 2022

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

Klein & Flanagan. *Nat Rev Immunol* 2016 16, 626-638 DOI: 10.1038/nri.2016.90

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

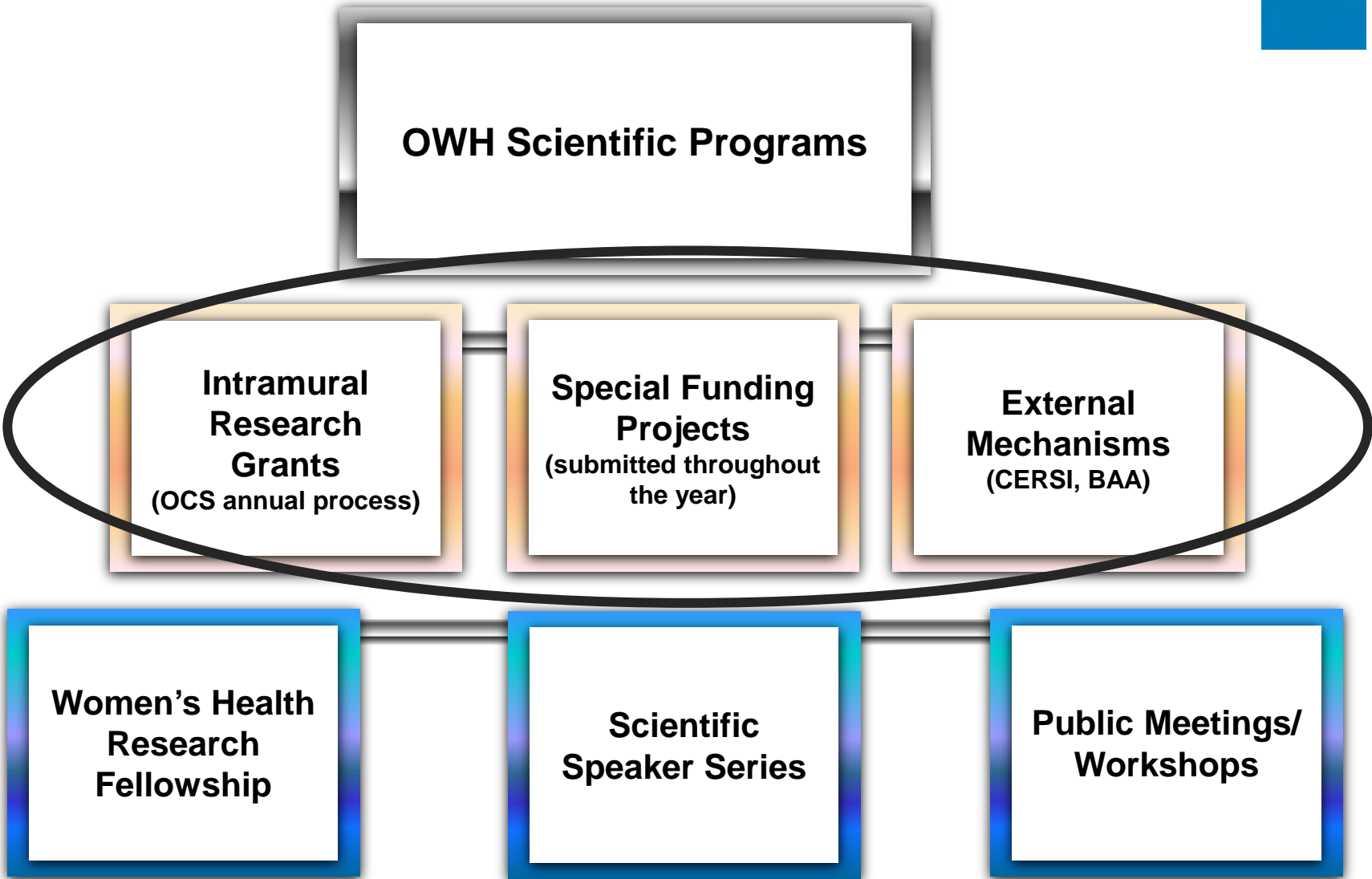
Center for
Drug
Evaluation
and
Research

Center for
Devices
and
Radiologic
Health

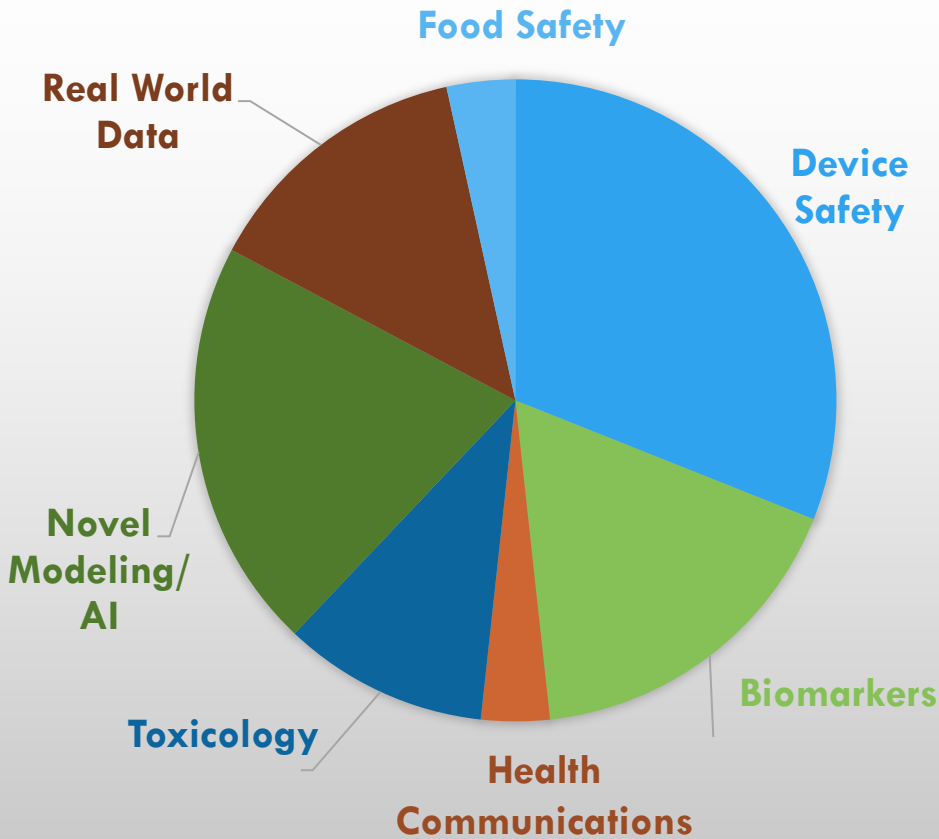
Center for
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Nutrition

National
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Toxicology
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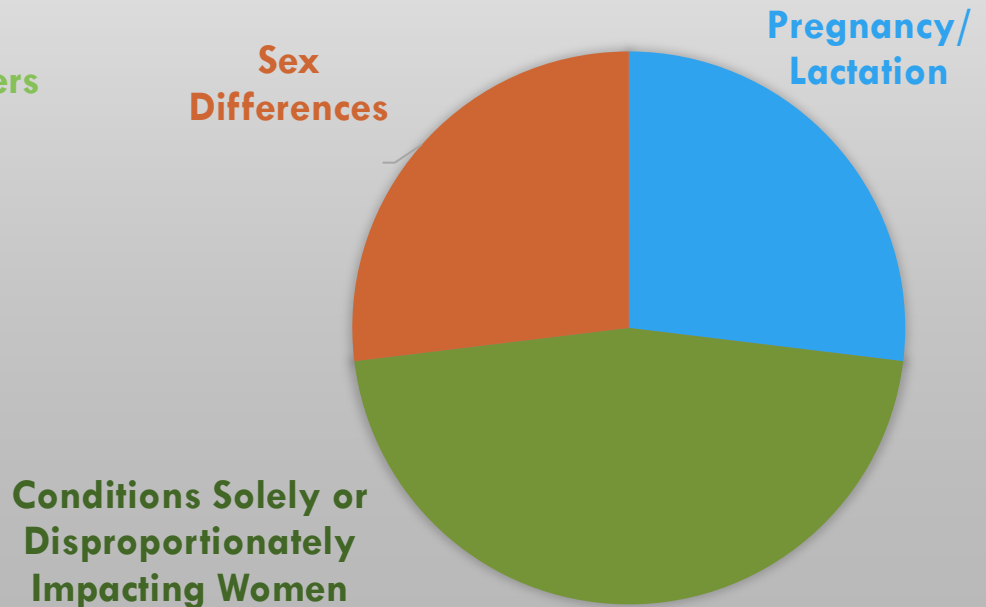


RESEARCH TOPIC/FIELD



Snapshot of Intramural Research Projects Funded by OWH FY2019-2021

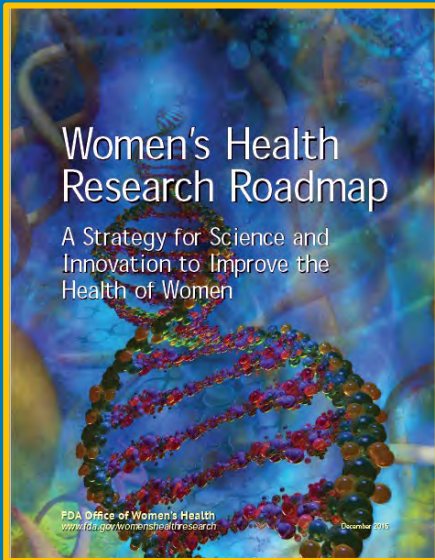
RESEARCH FOCUS



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)



RESEARCH ROADMAP

**Improved Regulatory
Decision-Making**

**Improved
Product Safety**

**Advancing Women's Health
and Public Health**

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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 *Women's Health Research Roadmap*

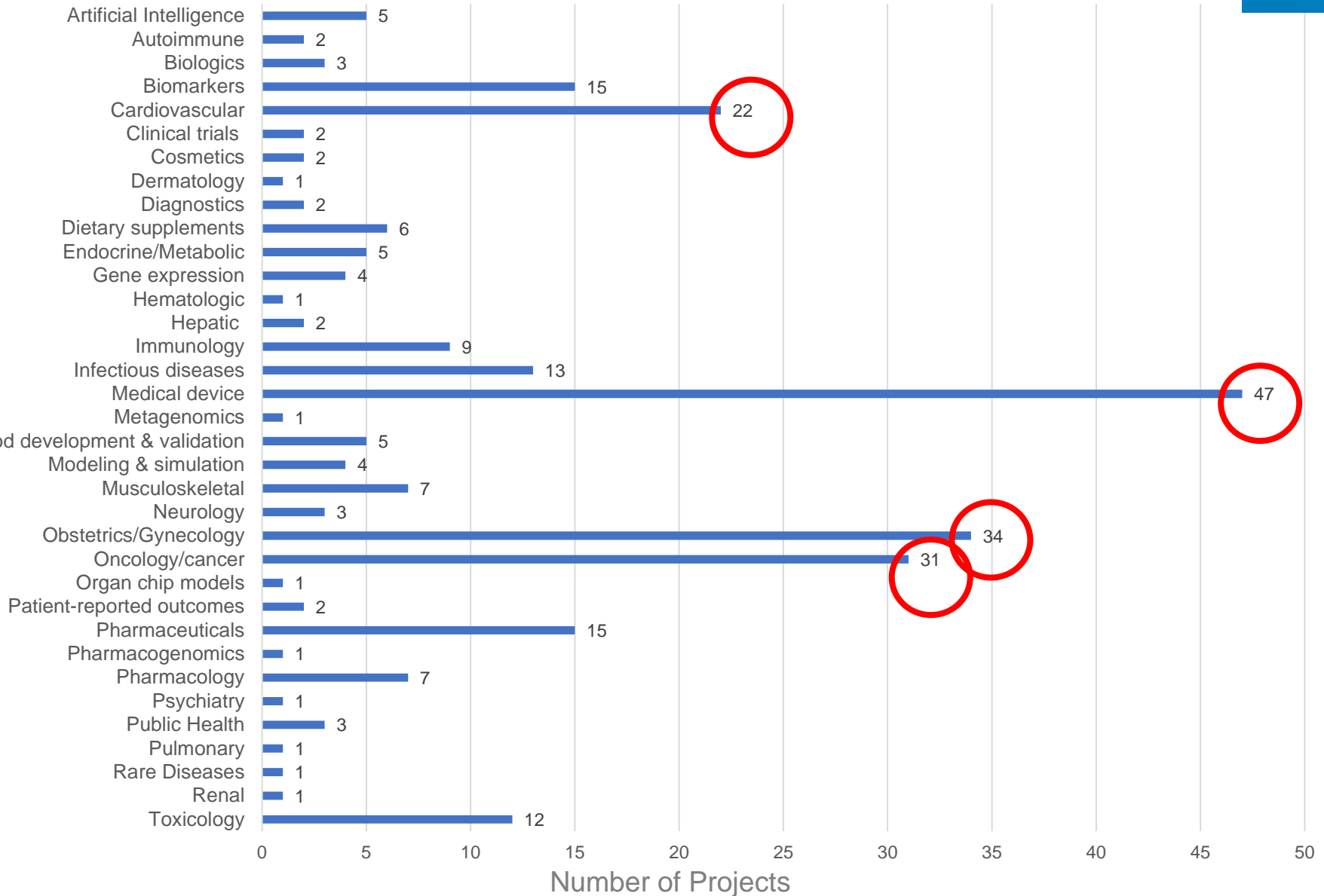
Read the Women's Health Research Roadmap:

<https://www.fda.gov/science-research/womens-health-research/womens-health-research-roadmap>

OWH Research Areas (FY2013-FY2023)



Project Tags



FY 2023 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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Questions?

