

# Office of Women's Health

## FDASIA 907 Action Plan Update

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**White Oak Campus**

**Silver Spring, MD**

**February 29, 2016**

# Office of Women's Health

## POLICY



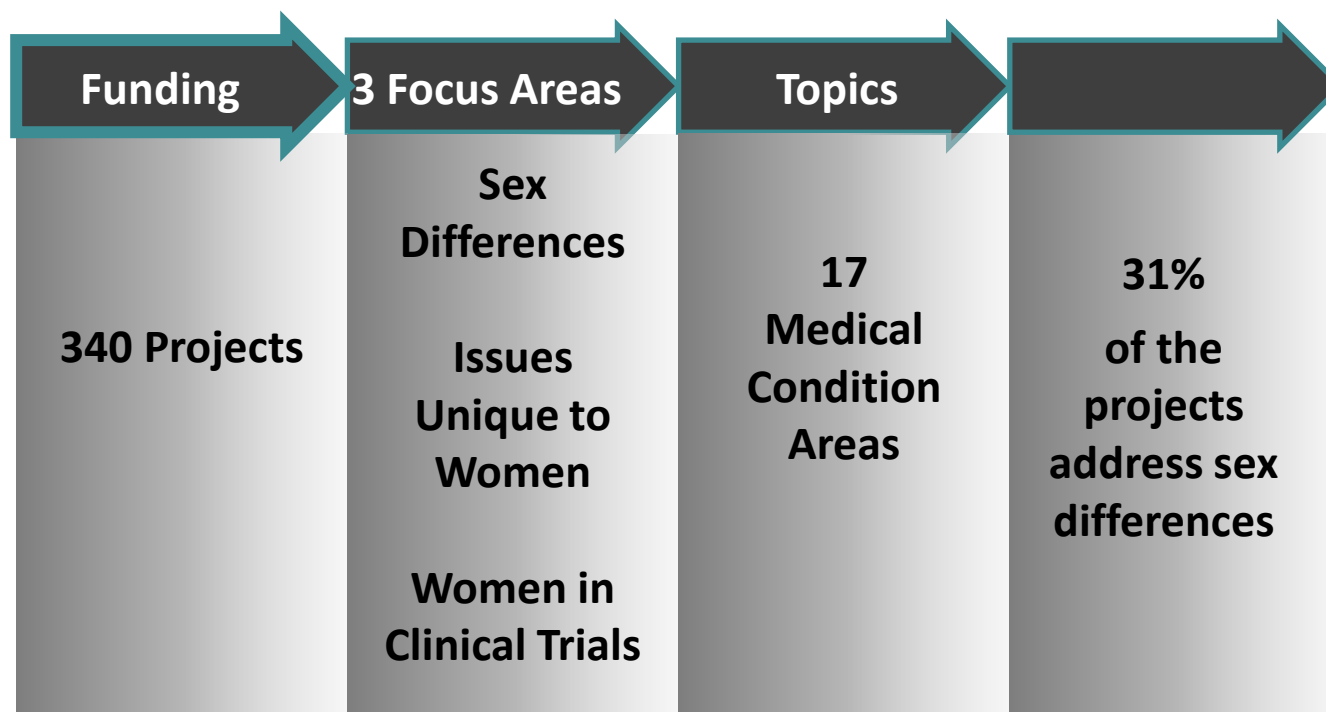
## SCIENCE



## OUTREACH

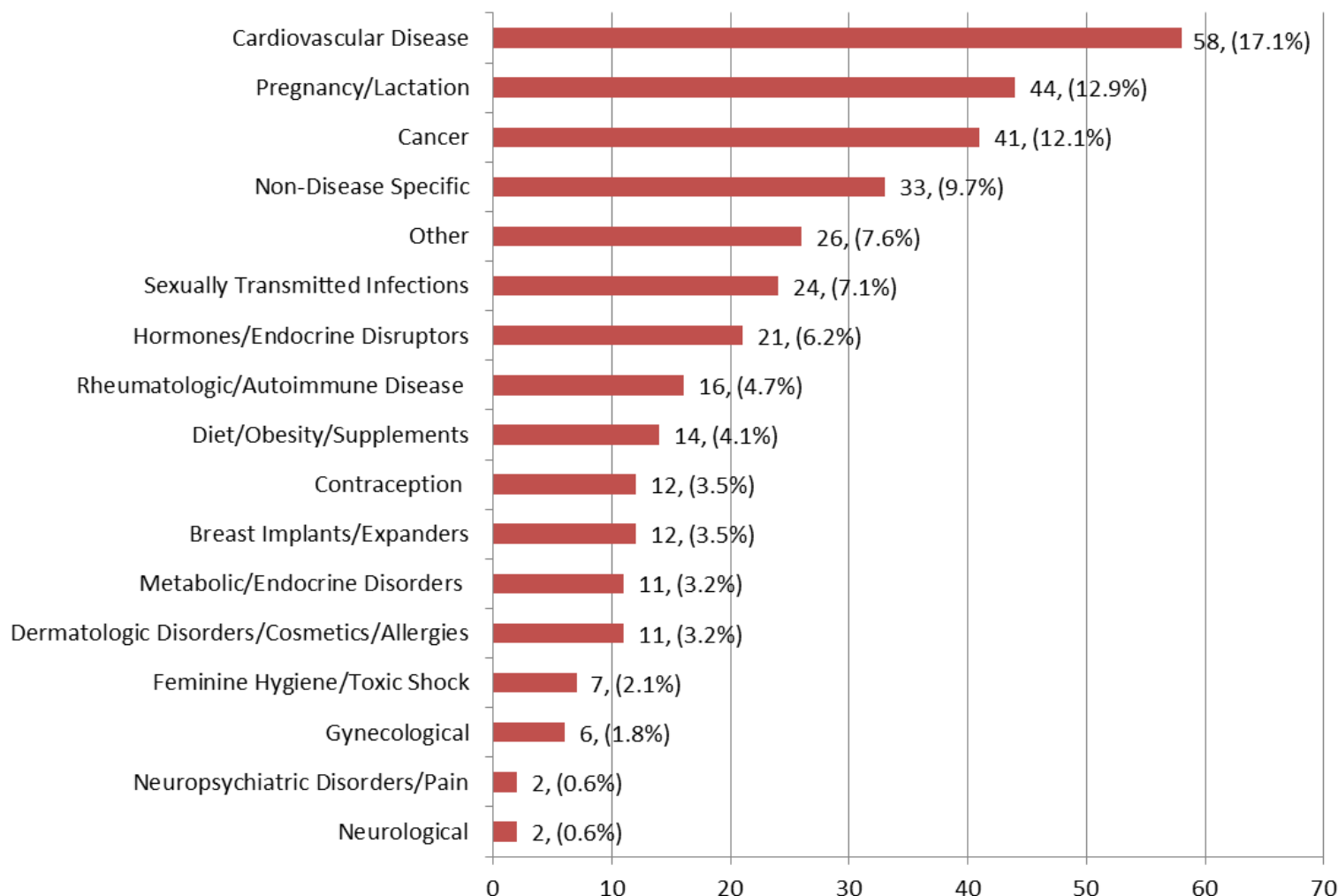


# OWH Research



# OWH-Funded Research

1994-2015

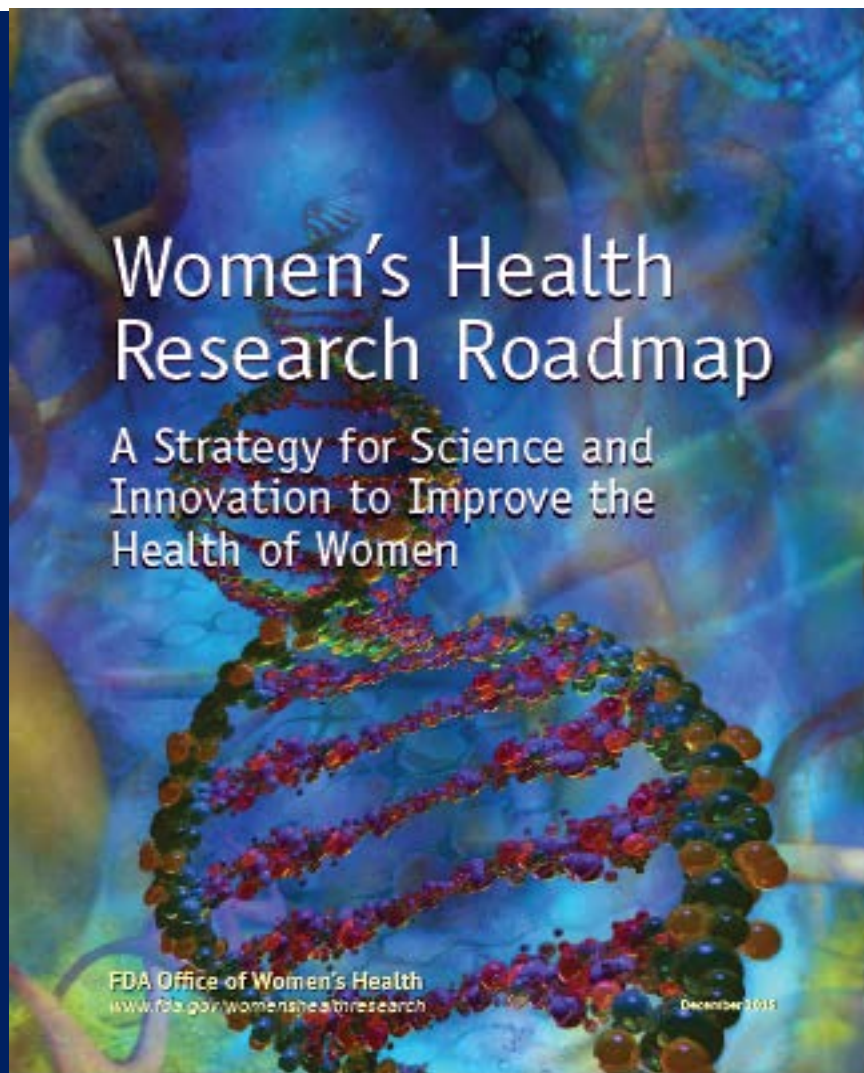


# FDAISA 907 Action Plan

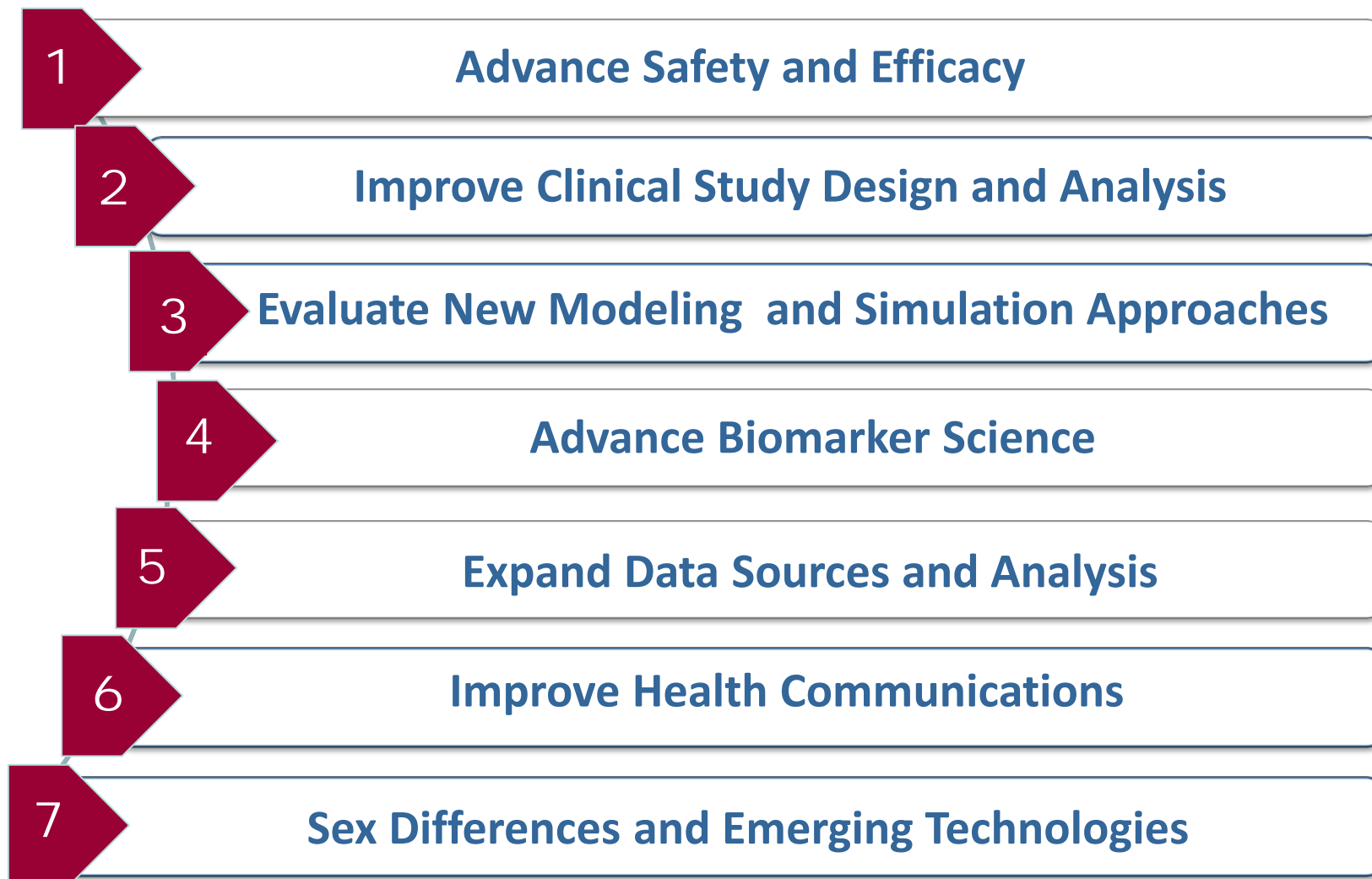
- **Quality**
  - Research
  - Dissemination
- **Transparency**
  - Data Tracking and Analysis
  - Collaborations
- **Participation**
  - Tools and Training
  - Clinical Trials Campaign



# New Action Item 1.5



# 7 Priority Areas





# **New Action Item 1.5**

## **Other OWH Research**

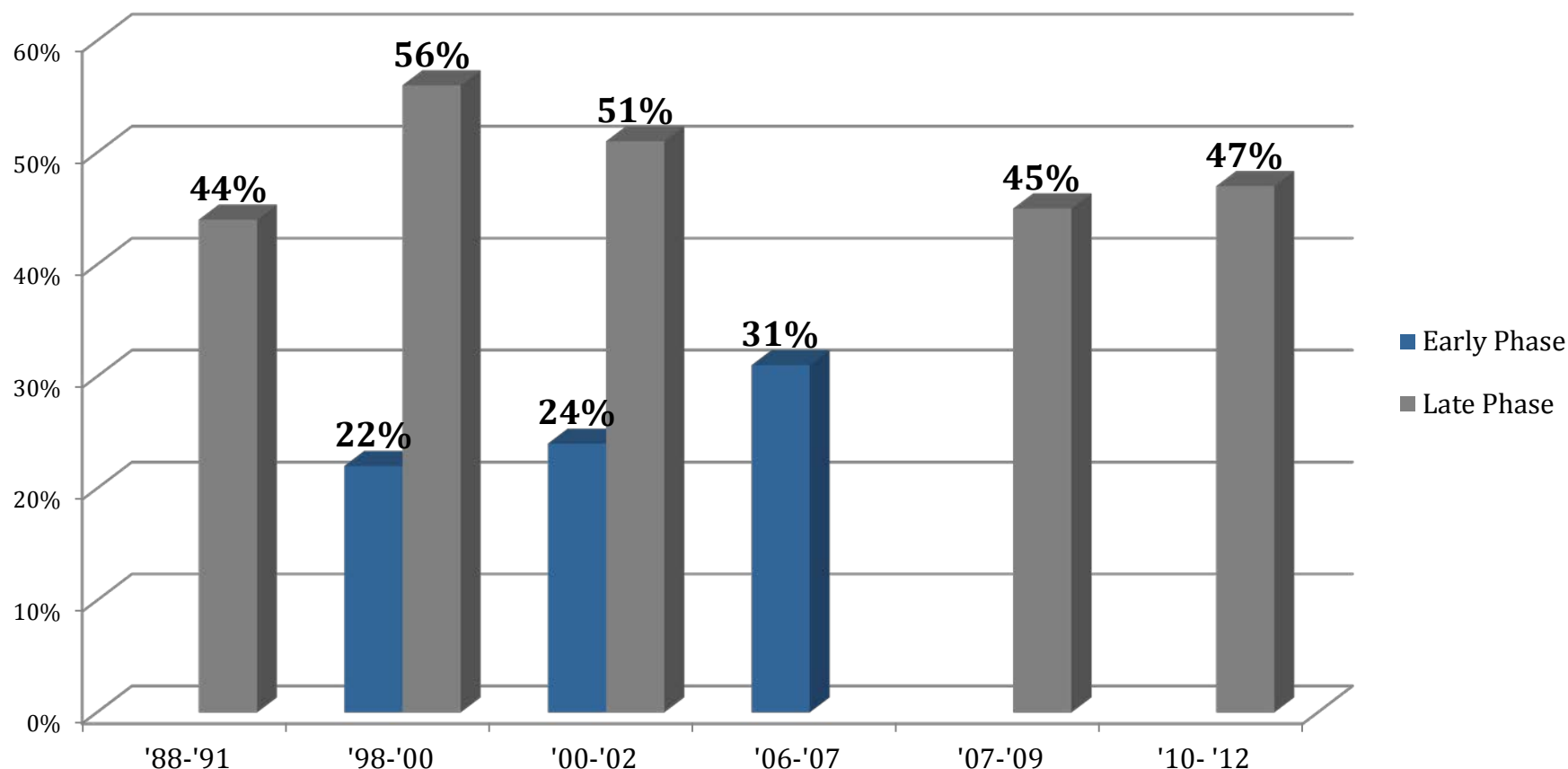
### **2015 Intramural Projects**

- Sex-specific outcomes with cardiac resynchronization therapy
- Individual patient-data meta-analysis and postmarket analysis as a method for improving data quality in demographic subgroups



# Data Tracking and Analysis

## % Women in Drug Clinical Trials



## New: Action Item 2.3

# Diverse Women in Clinical Trials Campaign

[www.fda.gov/womeninclinicaltrials](http://www.fda.gov/womeninclinicaltrials)

# Women in CLINICAL TRIALS

Make a Difference  
For Yourself and For Women Like You.

Ask your healthcare provider whether  
a clinical trial is right for you. Learn more  
at [www.fda.gov/womeninclinicaltrials](http://www.fda.gov/womeninclinicaltrials)



# Target Populations

- Older Women
- Women from Racial and Ethnic Groups
- Women with Disabilities
- Women with chronic health conditions:
  - Alzheimer's Disease/ Neurological Conditions
  - Cardiovascular Diseases/ Diabetes
  - Depression/ Anxiety
  - HIV
  - Lung diseases

# New: Clinical Trials Tools & Training

## Training Webinars



## Tools for Investigators



<http://orwh.od.nih.gov/toolkit/>

# New: Scientific Speaker Series

- **Represents**  
The scientific discoveries of sex and gender
- **Resource**  
Resource for FDA reviewers and leadership
- **Recognizes**  
Priority topics as identified by the Centers

**FDA Office of Women's Health**  
**Sex and Gender Specific Scientific Speaker Series**

**Sex Differences in CVD and Stroke**  
March 1, 2016 11:00 - 12:00  
Bldg 32, Room 2242

**"Sex and Gender in Cardiology: An Update"**  
Discussion of pivotal studies about treatment and diagnostics for myocardial infarction and the establishment of a databank about sex differences in drug utilization ([www.januscito.se/genderus/en/English/](http://www.januscito.se/genderus/en/English/))

**Karin Schenck-Gustafsson, Professor, MD, Ph.D., FEESC, Dr hc**  
Chair and founder, Centre for Gender Medicine  
Senior Professor of Cardiology, Senior Consultant Cardiology  
Karolinska Institutet and Karolinska University Hospital, Stockholm

**"Sex and Gender Differences in Stroke"**  
Discussion on emerging understanding of stroke aetiology, presentation and outcomes from the Karolinska Institutet Stroke Research Network

**Mia von Euler, MD, PhD**  
Associate professor of Neurology  
Head, Karolinska Institutet Stroke Research Network at Södersjukhuset





# Our Ongoing Commitment

## Science

- Research Roadmap
- Data Tracking, Analysis & Dissemination

## Professional Education

- NIH Toolkit Collaboration
- On-line Continuing Education

## Consumer Outreach

- Clinical Trials Campaign
- Multi-media Communications





Join Us

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