Office of Women’s Health
FDASIA 907 Action Plan Update

Marsha B. Henderson, M.C.R.P.
Assistant Commissioner for Women’s Health

White Oak Campus
Silver Spring, MD
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OWH Research

340 Projects

Sex Differences
Issues Unique to Women
Women in Clinical Trials

17 Medical Condition Areas

31% of the projects address sex differences
OWH-Funded Research
1994-2015

- Cardiovascular Disease: 58, (17.1%)
- Pregnancy/Lactation: 44, (12.9%)
- Cancer: 41, (12.1%)
- Non-Disease Specific: 33, (9.7%)
- Other: 26, (7.6%)
- Sexually Transmitted Infections: 24, (7.1%)
- Hormones/Endocrine Disruptors: 21, (6.2%)
- Rheumatologic/Autoimmune Disease: 16, (4.7%)
- Diet/Obesity/Supplements: 14, (4.1%)
- Contraception: 12, (3.5%)
- Breast Implants/Expanders: 12, (3.5%)
- Metabolic/Endocrine Disorders: 11, (3.2%)
- Dermatologic Disorders/Cosmetics/Allergies: 11, (3.2%)
- Feminine Hygiene/Toxic Shock: 7, (2.1%)
- Gynecological: 6, (1.8%)
- Neuropsychiatric Disorders/Pain: 2, (0.6%)
- Neurological: 2, (0.6%)
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

Women’s Health Research Roadmap
A Strategy for Science and Innovation to Improve the Health of Women

FDA Office of Women’s Health
www.fda.gov/womenshealthresearch
December 2011
7 Priority Areas

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. Sex Differences and Emerging Technologies
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

<table>
<thead>
<tr>
<th>Year</th>
<th>Early Phase</th>
<th>Late Phase</th>
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<tbody>
<tr>
<td>'88-'91</td>
<td>44%</td>
<td>56%</td>
</tr>
<tr>
<td>'98-'00</td>
<td>22%</td>
<td>51%</td>
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<tr>
<td>'00-'02</td>
<td>24%</td>
<td>31%</td>
</tr>
<tr>
<td>'06-'07</td>
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<td>45%</td>
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<tr>
<td>'07-'09</td>
<td>45%</td>
<td>47%</td>
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<tr>
<td>'10-'12</td>
<td>47%</td>
<td>51%</td>
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New: Action Item 2.3
Diverse Women in Clinical Trials Campaign
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
Collective Approach

FDA

Community

Industry

Healthcare Professionals
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

- Website: www.fda.gov/womens
- Twitter: @FDAWomen
- Pinterest: www.pinterest.com/usfda/womens-health/