Women in Clinical Trials: FDA Perspective

CTTI Meeting 10/21/2021

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Director, Office of Women's Health
U.S. Food and Drug Administration

FDA U.S. FOOD & DRUG ADMINISTRATION

Disclaimer

The views expressed are those of the speaker and do not necessarily reflect official policy of the US FDA. No official endorsement by the US FDA is intended or should be inferred.

Our 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 data analysis
- **Identify and monitor the progress of crosscutting and multidisciplinary women's health initiatives** including changing needs, areas that require study, and new challenges to the health of women as they relate to FDA's mission
- **Serve as the principal advisor** to the Commissioner and other key Agency officials on **scientific, ethical, and policy issues** relating to women's health

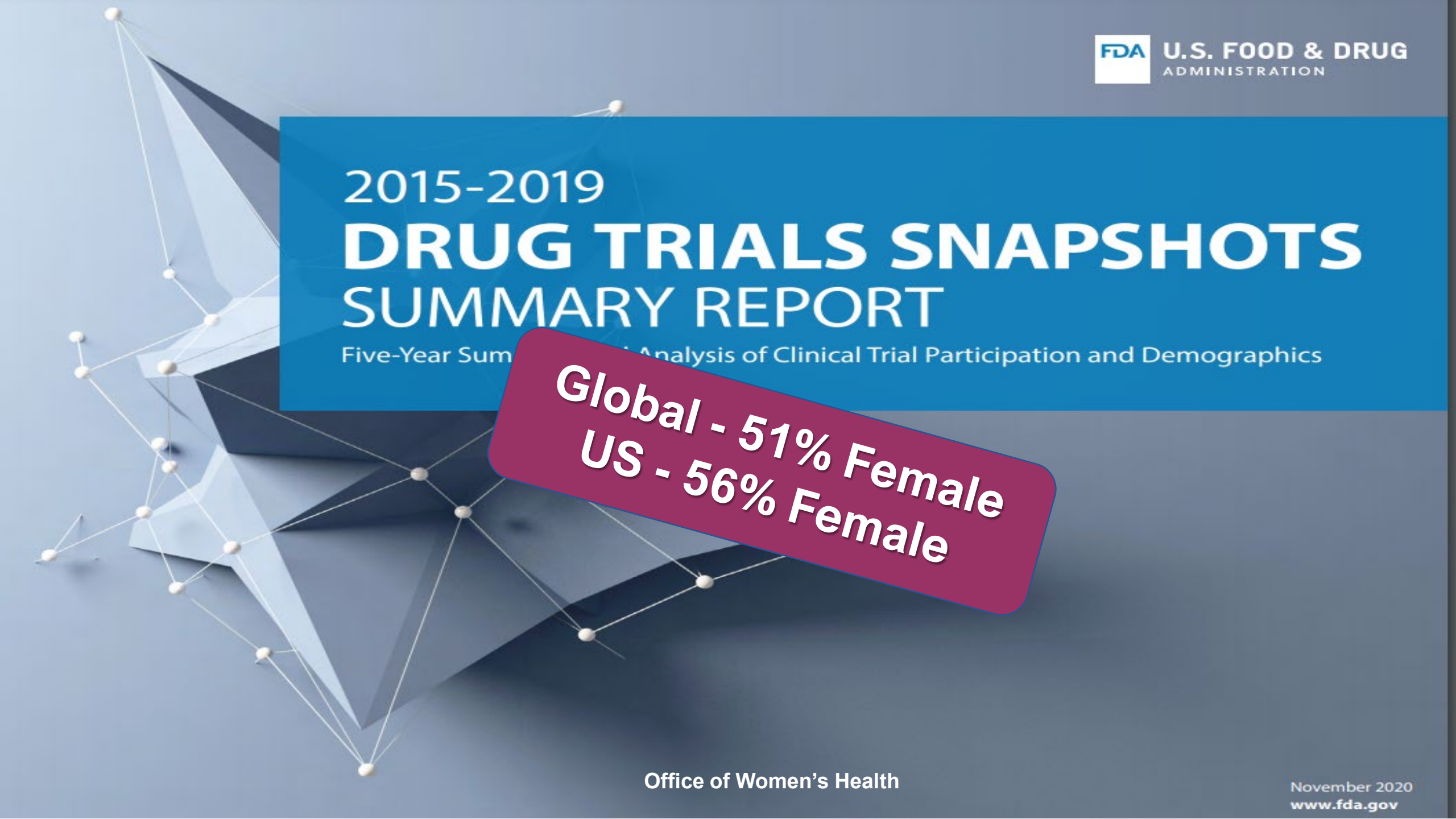
Office of Women's Health

SCIENCE

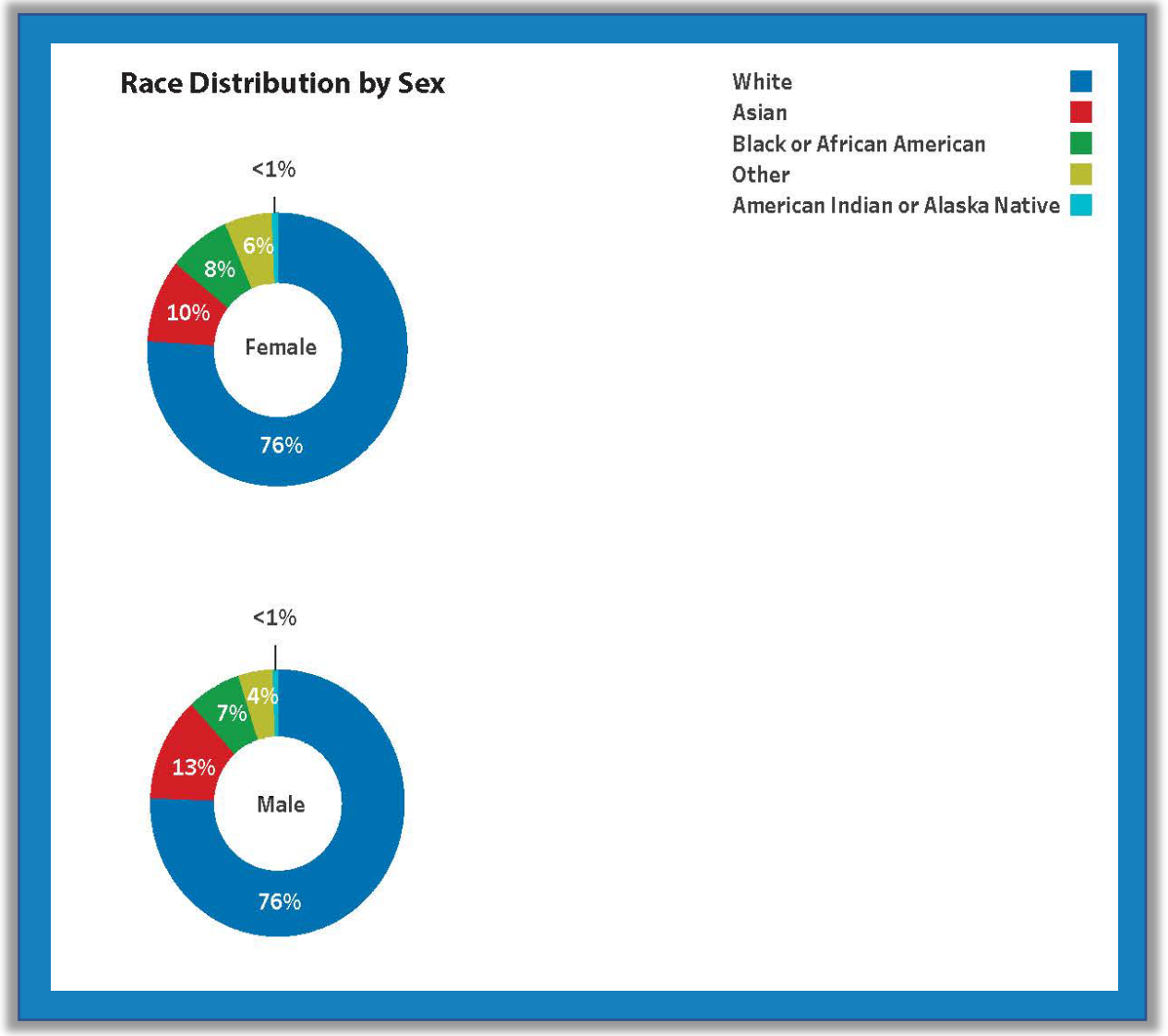
EDUCATION

ENGAGEMENT

OWH achieves its mission through the foundational principle that Sex is a Biological Variable (SABV)

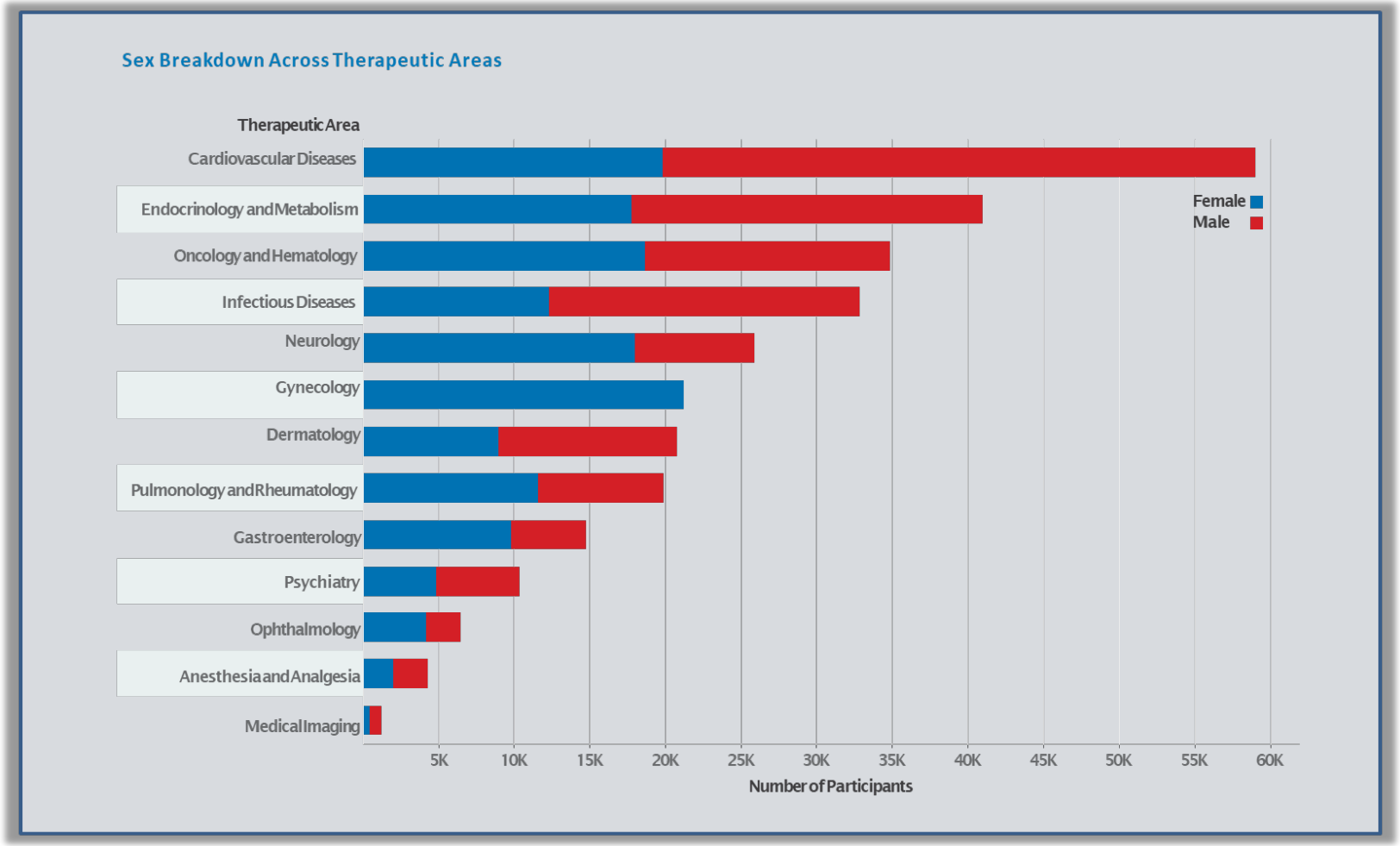

FDA
U.S. FOOD & DRUG
ADMINISTRATION
2015-2019
DRUG TRIALS SNAPSHOTS
SUMMARY REPORT
Five-Year Sum
Analysis of Clinical Trial Participation and Demographics
Global - 51% Female
US - 56% Female
Office of Women's Health
November 2020
www.fda.gov

2015-2019 Drug Trials Snapshots Summary Report

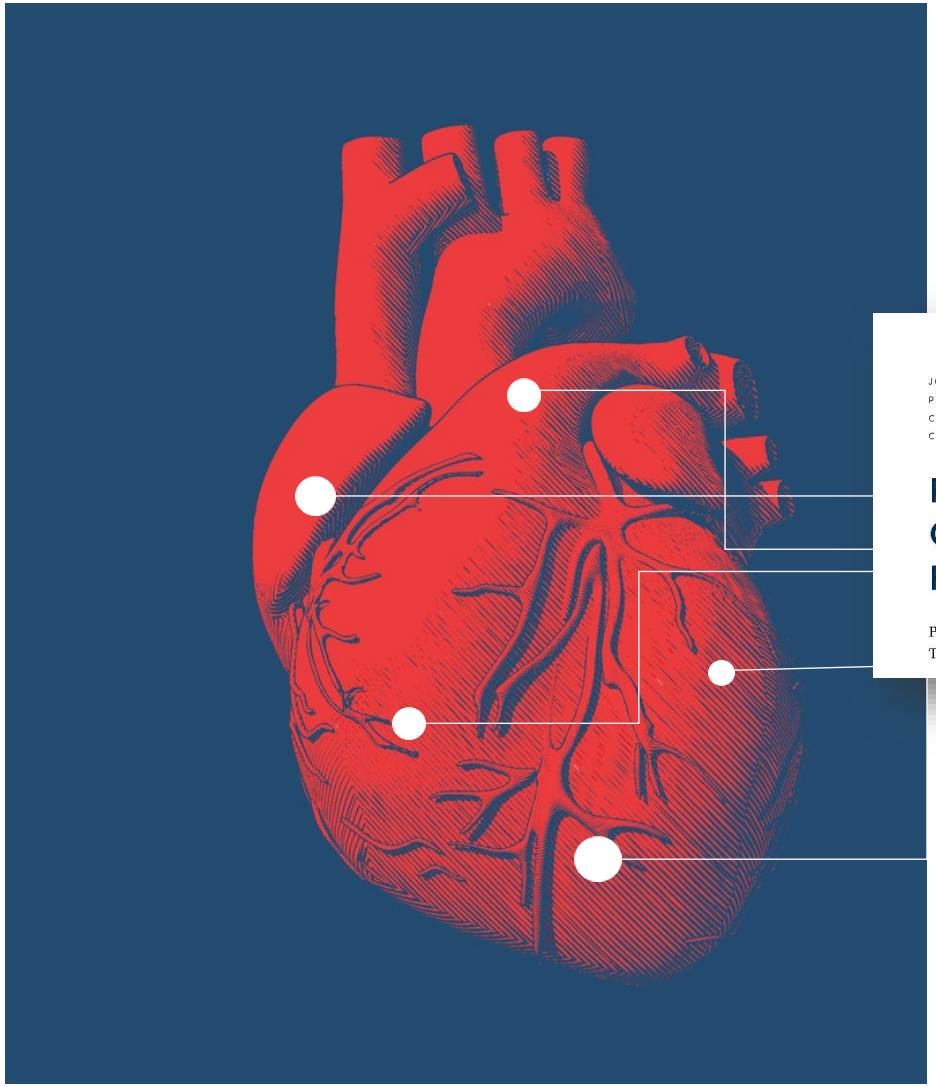


Office of Women's Health

2015-2019 Drug Trials Snapshots Summary Report



Office of Women's Health



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Participation of Women in Clinical Trials Supporting FDA Approval of Cardiovascular Drugs

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Office of Women's Health

Diverse Women in Clinical Trials

WOMEN IN CLINICAL TRIALS = HOPE

Clinical trials are research studies that help to show whether a test or treatment works and is safe. There are many ways you can take part in a trial. Some trials ask you questions about treatments you already take. In other trials, you take a new drug. Some clinical trials use healthy people. Others use people who have a specific health problem.

Ask your healthcare provider if a clinical trial is right for you.

Are Women in Clinical Trials?

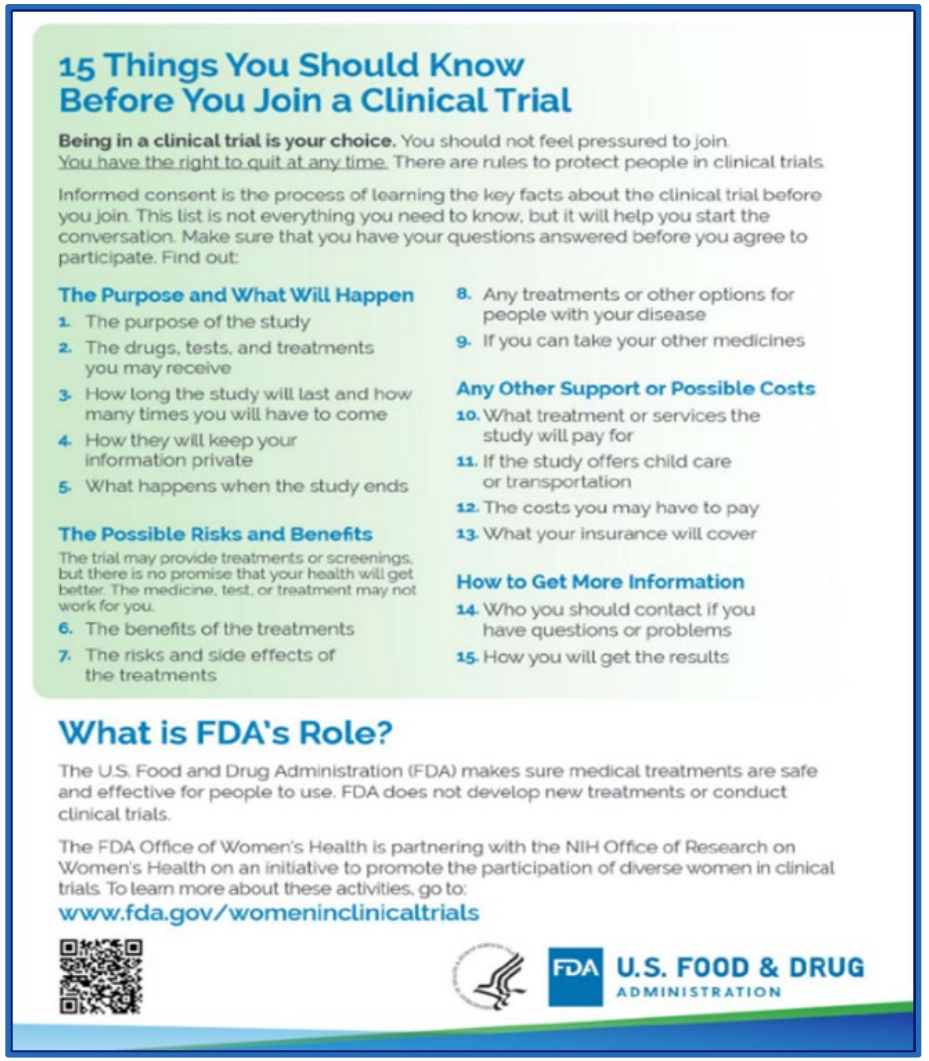
Yes. Women are already in clinical trials. However, women from diverse backgrounds still need to participate. Women of all ages, racial and ethnic groups, and women with disabilities or chronic health conditions should think about being in a clinical trial.

You can help by considering a trial for yourself. You can make a difference by helping doctors learn more about women's health.

Why Should Women Participate?

Medical products can affect men and women differently. It is important that women participate because women sometimes have different side effects. A woman's body can also affect how drugs and devices work.

FDA Office of Women's Health
www.fda.gov/womeninclinicaltrials



15 Things You Should Know Before You Join a Clinical Trial

Being in a clinical trial is your choice. You should not feel pressured to join. You have the right to quit at any time. There are rules to protect people in clinical trials.

Informed consent is the process of learning the key facts about the clinical trial before you join. This list is not everything you need to know, but it will help you start the conversation. Make sure that you have your questions answered before you agree to participate. Find out:

The Purpose and What Will Happen

1. The purpose of the study
2. The drugs, tests, and treatments you may receive
3. How long the study will last and how many times you will have to come
4. How they will keep your information private
5. What happens when the study ends

The Possible Risks and Benefits

The trial may provide treatments or screenings, but there is no promise that your health will get better. The medicine, test, or treatment may not work for you.

6. The benefits of the treatments
7. The risks and side effects of the treatments
8. Any treatments or other options for people with your disease
9. If you can take your other medicines

Any Other Support or Possible Costs

10. What treatment or services the study will pay for
11. If the study offers child care or transportation
12. The costs you may have to pay
13. What your insurance will cover

How to Get More Information

14. Who you should contact if you have questions or problems
15. How you will get the results

What is FDA's Role?

The U.S. Food and Drug Administration (FDA) makes sure medical treatments are safe and effective for people to use. FDA does not develop new treatments or conduct clinical trials.

The FDA Office of Women's Health is partnering with the NIH Office of Research on Women's Health on an initiative to promote the participation of diverse women in clinical trials. To learn more about these activities, go to:
www.fda.gov/womeninclinicaltrials

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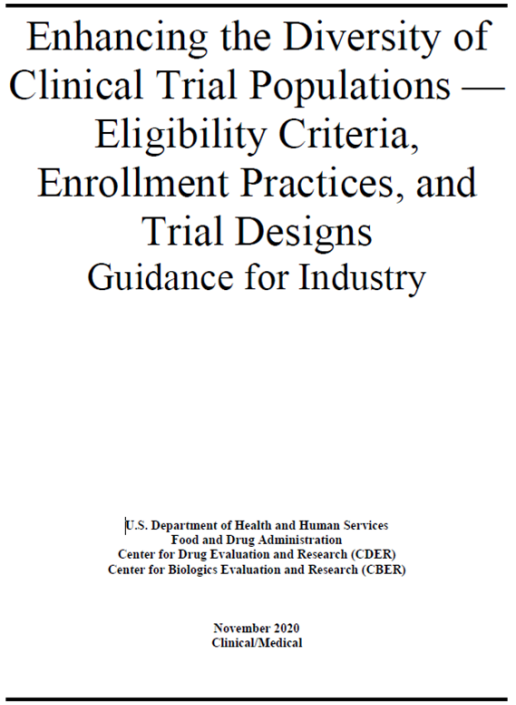
Office of Women's Health

FDA Guidance for Industry

Representatives of both sexes should be included in clinical trials in numbers adequate to allow detection of clinically significant sex-related differences in drug response.

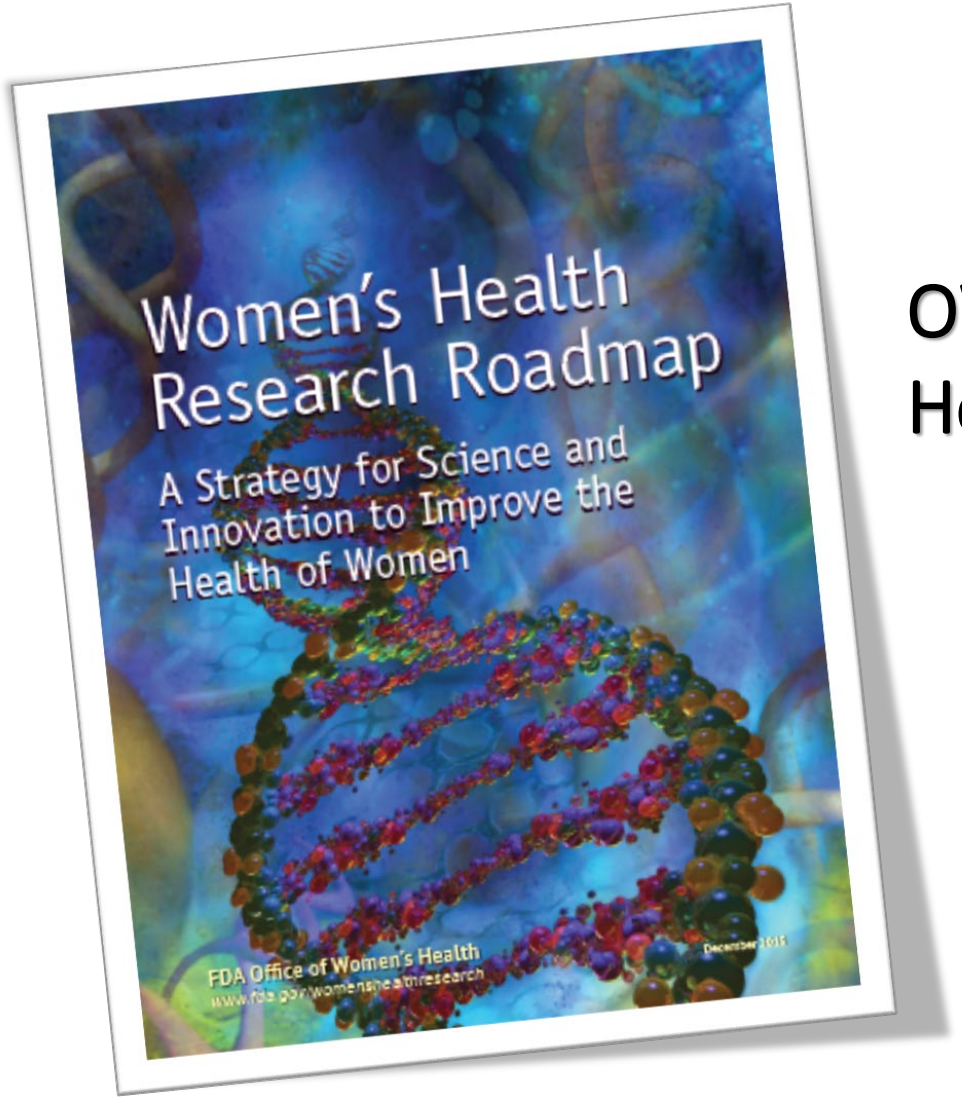


Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs

Guidance for Industry

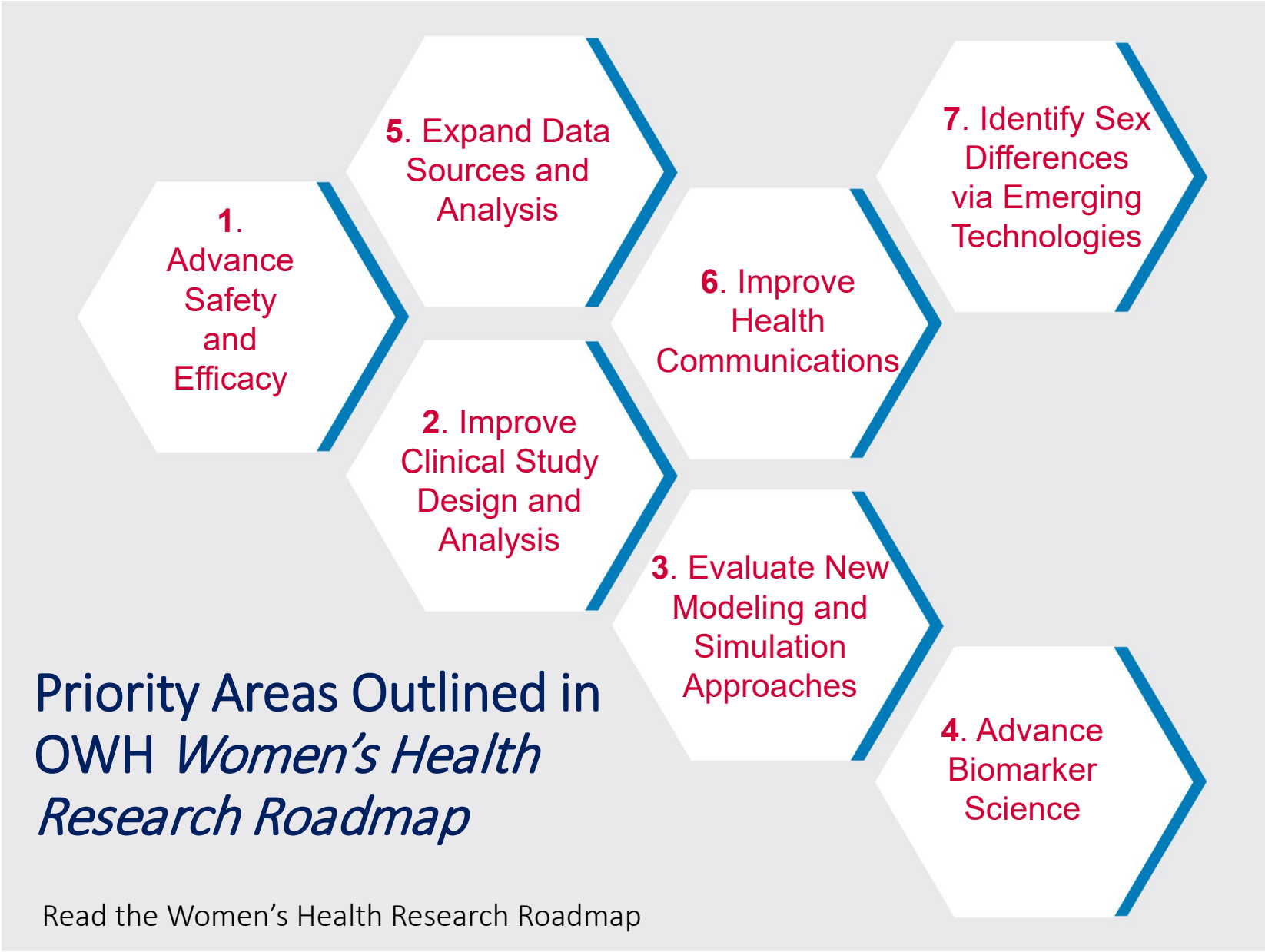
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

November 2020
Clinical/Medical



OWH created the first FDA Women's Health Research Roadmap

http://inside.fda.gov:9003/downloads/scienceresearch/specialtopics/womenshealthresearch/ucm479681.pdf



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

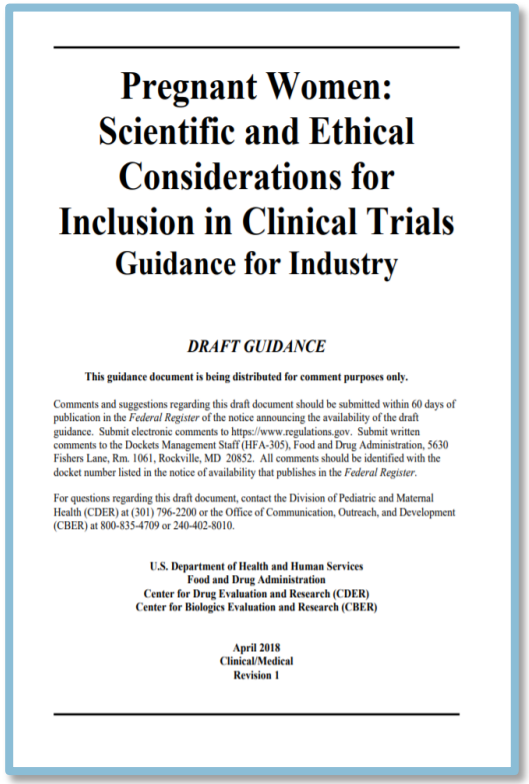
Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

The 21st Century Cures Act P.L. 114-255

- Advise the Secretary of Health and Human Services (HHS) regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women
- OWH serves as the FDA lead to the Task Force
- 15 recommendations
- Implementation of recommendations report – Summer 2020

https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/21stCenturyCuresAct/default.htm

Related FDA Guidance



Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials
Guidance for Industry

DRAFT GUIDANCE

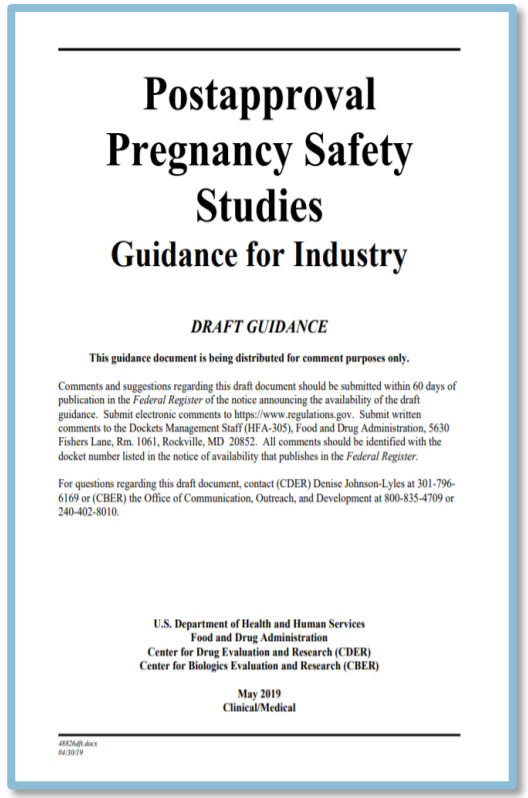
This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact the Division of Pediatric and Maternal Health (CDER) at (301) 796-2200 or the Office of Communication, Outreach, and Development (CBER) at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

April 2018
Clinical/Medical
Revision 1



Postapproval Pregnancy Safety Studies
Guidance for Industry

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For questions regarding this draft document, contact (CDER) Denise Johnson-Lyles at 301-796-6169 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2019
Clinical/Medical

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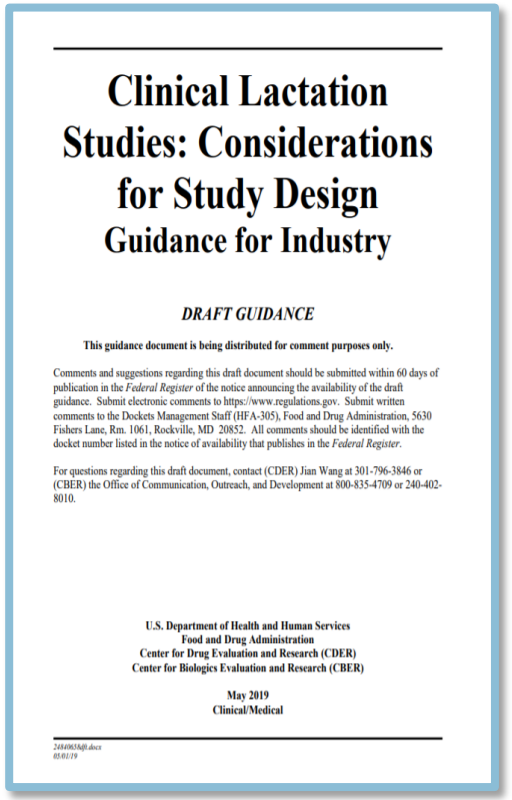

Clinical Lactation Studies: Considerations for Study Design
Guidance for Industry

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For questions regarding this draft document, contact (CDER) Jian Wang at 301-796-3846 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

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Food and Drug Administration
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May 2019
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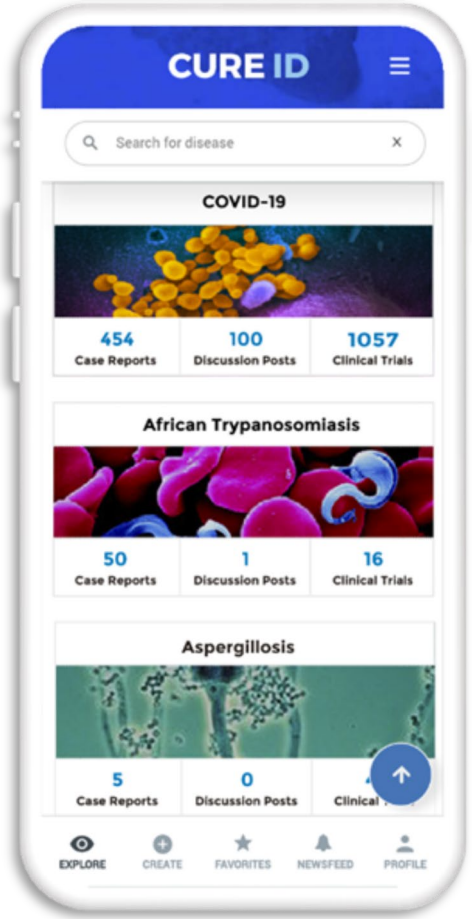
FDA Office of Women's Health Pregnancy Registries Webpage

www.fda.gov/pregnancyregistries

- Connects pregnant women and health professionals to ~123 registries
- Links to drug information
- Patient education resources
- www.fda.gov/pregnancyregistries



- **CURE ID app:** Reporting novel uses of existing drugs

Visit :https://cure.ncats.io/

Available NOW: Free Online Courses Addressing Sex and Gender

Developed by the NIH Office of Research on Women's Health in partnership with the FDA Office of Women's Health

Bench to Bedside: Integrating Sex and Gender to Improve Human Health

Explore sex- and gender-related differences in human health and disease.

Register at https://go.usa.gov/xvGwn.

NIH National Institutes of Health
Office of Research on Women's Health

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OFFICE OF WOMEN'S HEALTH

nih.gov/women

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Advancing the Health of Women Through Science

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