FDA
Office of Women’s Health (OWH)

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FDA Office of Women’s Health (OWH)

- Created in 1994 by Congressional mandate to:
  - Correct gender disparities in FDA drug, device, biologics testing and regulation policy
  - Oversee the implementation of revised clinical trial guidelines with respect to representation of women
FDA OWH Mission

- Protect and advance the health of women through policy, science, and outreach
- Advocate for inclusion of women in clinical trials and analysis of sex/gender effects
Why is OWH interested in the Transradial Thinktank?

- Studies have shown that women greater risk of bleeding complications than men with some medical devices

- Example of OWH funded project: “Risk of local adverse events by gender following cardiac catheterization”
What OWH would like the Registry to capture/analyze

- Age, Race, Sex data
- Analysis of data by sex/gender
Questions, please call/e-mail

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