

# The Import and Challenges of Open Science: A Patient View

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# WomenHeart: The National Coalition for Women with Heart Disease

- ♥ The nation's only patient-centered organization serving the 43 million American women living with or at risk of heart disease
- ♥ Founded in 1999 by three women heart attack survivors, concerned about:
  - Misdiagnosis
  - Delays and disparities in care
  - Feelings of fear and isolation
  - Very little information/support



## Mission & What We Do

*To improve the health and quality of life of women living with or at risk of heart disease and to advocate for their benefit*

- ♥ **Educate** women on the importance of taking charge of their heart health
- ♥ **Support** women living with heart disease and connect them with one another
- ♥ **Advocate** for research funding and policies that meet the needs of women with heart disease
- ♥ **Partner** with hospitals committed to advancing women's heart health nationwide

## Who We Are & Why We Are Different

- ♥ Real women – the “boots on the ground” in the fight against heart disease
- ♥ A community of thousands of members nationwide, including women heart patients, their families, physicians and health advocates all committed to helping women live longer, healthier lives.

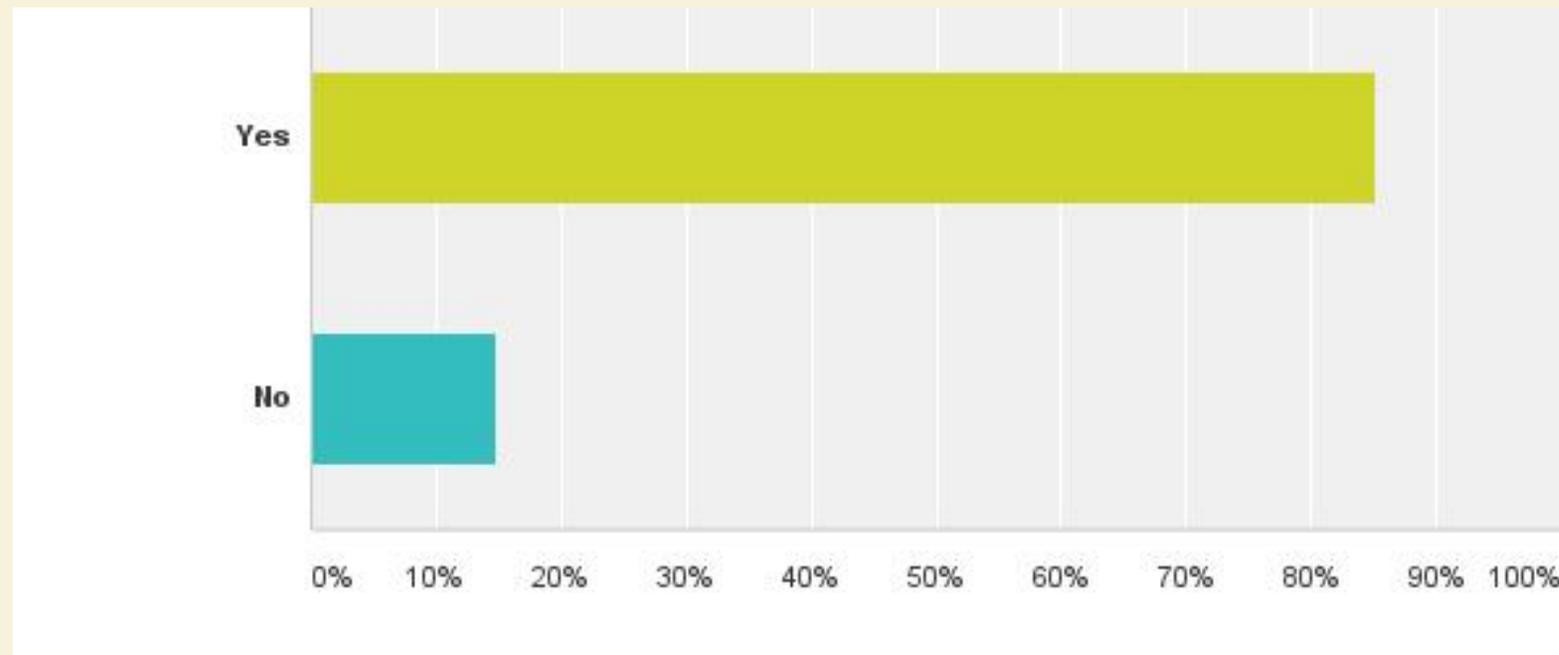


## Goals for Medical Device Evaluation and Approval

- ♥ Patient participation and preference are indispensable to the device development, evaluation and approval process.
- ♥ Sharing data as part of the evaluation and approval process will enhance the study of sex differences and may result in safer and more effective products for women.
- ♥ Patients prioritize approving safer and more effective devices that work well in women over faster and more efficient pathways to approval without robust data on women.
- ♥ Sharing data on devices by age, sex and race will assist providers and patients as they make treatment decisions.

# Survey of women living with heart disease: April 8-10, 2016 61 responses

Q1: If you have or were to receive a medical device, would you give consent for your data to be shared?



## Q2: What questions would need to be addressed before you agreed to participate?

Reponses focused on the following issues:

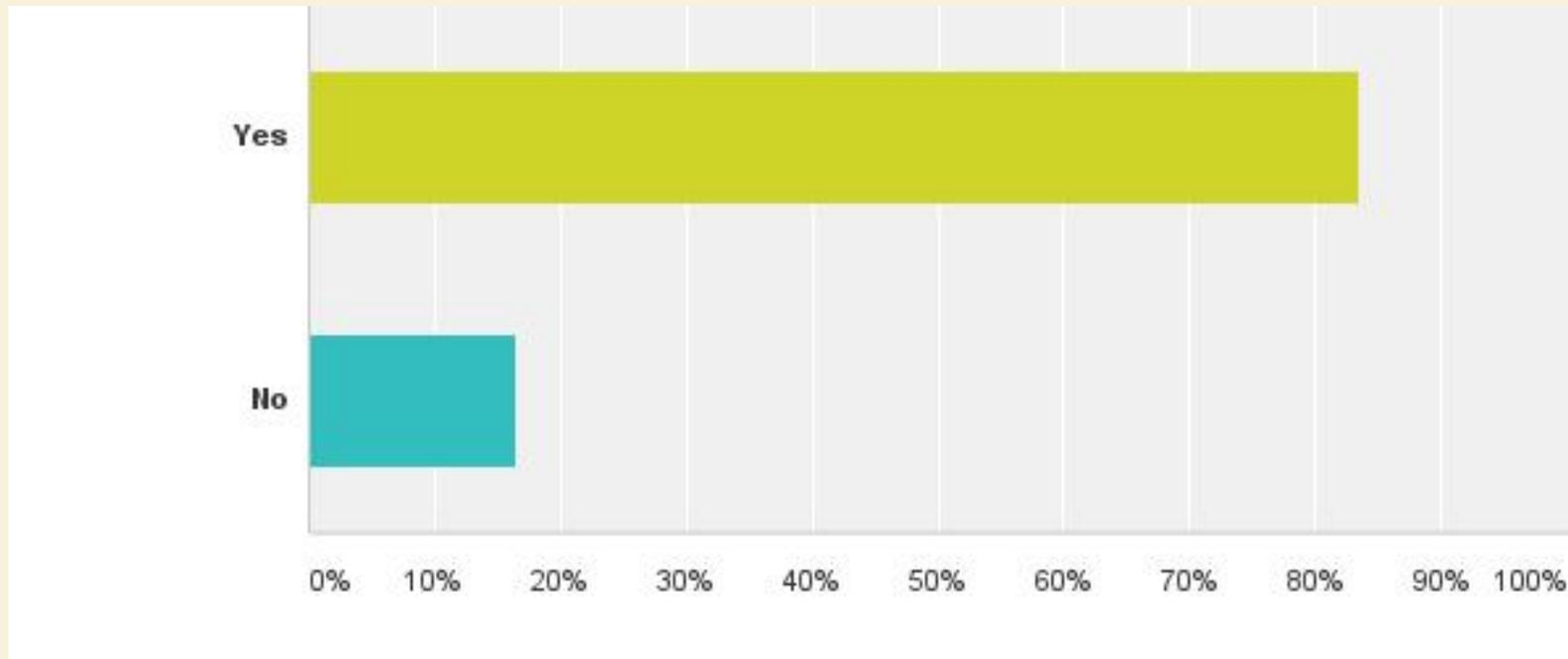
- ♥ Privacy and security of data
- ♥ Use of data with time limits
- ♥ Concern about safety of social security numbers
- ♥ Availability of feedback

## Q3: If you did not give permission, what would your greatest concerns be?

Responses focused on the following issues:

- ♥ Compromised privacy of social security numbers
- ♥ Possibility of selling or misusing data
- ♥ Concern that information would be used against the patient
- ♥ Concern about missing an opportunity to help other women

Q4: Can you see advantages or improvements this would have over the current system?



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Responses focused on the following issues:

- ♥ The addition of information to the database about current devices in women
- ♥ The creation of a larger population to enable subgroup analysis of women
- ♥ The development of individualized information for patients
- ♥ Data sharing as a tool for treatment decisions, patient care and health outcomes

## Patients are the key stakeholders

- ♥ WomenHeart is eager to work with the FDA, providers and industry to ensure that patient preference is carefully considered.
- ♥ WomenHeart remains committed to ensuring that patient participation in clinical trials and pre/post market evaluations is a priority and remains an essential element of our education and advocacy efforts.

*“My cardiologist saved my heart, but  
WomenHeart saved my life.”*

*WomenHeart Champion*

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# Women Heart

The National  
Coalition for Women  
with Heart Disease

[www.womenheart.org](http://www.womenheart.org)

