



# **Subgroup Analysis: What is it and Why We Should Care?**

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# Once Upon a Time.....The Ambien Story

- 1992 -- FDA approves Ambien for treatment of insomnia.
- Millions of Americans started taking Ambien to help them sleep at night.
- Reports of drowsiness after taking Ambien and many complaints of car accidents as a result.

# Once Upon a Time.....The Ambien Story cont.

- Studies found that for women, Ambien stays in the body longer than men.
- Women were more likely than men to be impaired the next morning and so more likely to drive impaired than men.
- 2013 -- FDA announced that the Ambien dosage should be halved for women.

## **Moral of the Story**

**“When we fail to consider sex and gender, we are leaving women’s health to chance.”**

# What is a Subgroup?

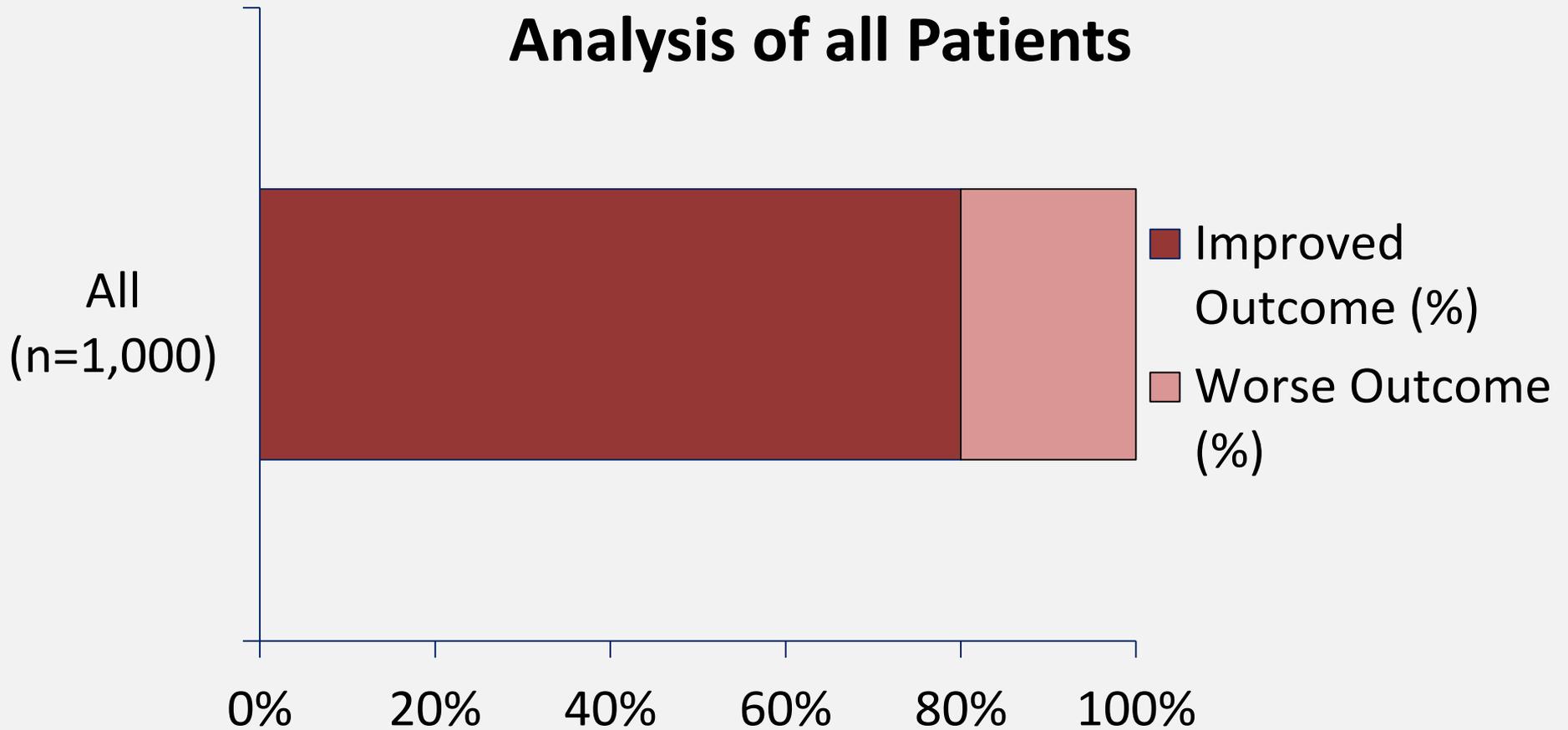
- A subset of people drawn from a larger group  
Eg. Sex, Race, Ethnicity, Age, people with diabetes.

## What is Subgroup Analysis?

- Analyzing safety and effectiveness information separately for a subset of people.

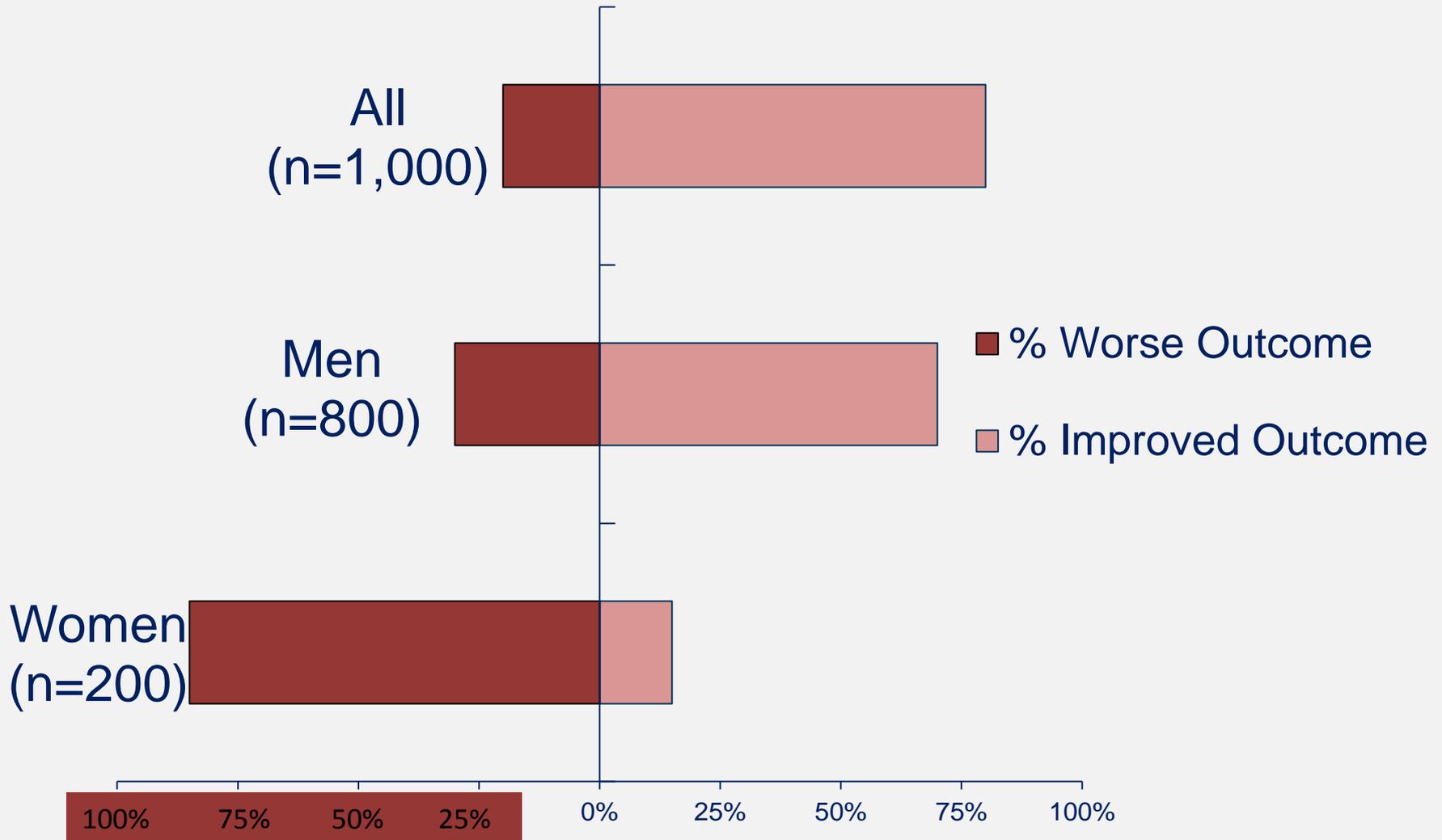
# Subgroup Analysis: Why We Should Care

## Analysis of all Patients



# Subgroup Analysis: Why We Should Care

## Subgroup analysis by sex



# Demographic Inclusion: Subgroup Analysis' Twin Sister



# The Problem

- Cardiovascular Disease is the #1 killer of women in the U.S.
  - BUT less than 1 in 3 patients in cardiovascular clinical trials are female.
  - AND less than one-third of cardiovascular clinical trials do subgroup analysis.
- African Americans are 13% of the U.S. population but only 5% of clinical trial participants.
- Hispanics make up 16% of the population but only 1% of clinical trial participants.
- In most studies, this is too few to do a meaningful subgroup analysis.

# Why is Demographic Inclusion Important?

- Our understanding of how diseases work is improved by looking at the impact of sex, race, ethnicity, and age.
- Genetic differences affect how minority groups respond to treatment for some diseases.
- It's important to have large enough numbers of different groups to do subgroup analyses for safety and effectiveness.

# Why is Demographic Inclusion Important?

- We need to know if drugs and devices are safe and effective for **EVERYONE**.
- People of color and women and older patients have been historically underrepresented in clinical trials in the U.S.

# Why is the FDA Important?

- Federal law require HHS to include diverse populations in research studies.
- **BUT** -- FDA is only health agency that is exempted from these federal requirements
  - Rationale: Studies submitted to FDA for approval are done and paid for by private companies NOT taxpayers.
- **BUT** -- FDA is responsible for ensuring the safety and effectiveness of medical products that touch each one of our lives.

# Implications For OUR Health

- We need substantial numbers of subgroups to know if a treatment is safe and effective for people like them.
- Presents unknown risks and benefits to some groups more than others.
- Limits potential to discover treatments that may be important to the types of patients who were excluded from studies.

**QUESTIONS??**