Will This Treatment Work for Me?

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What is subgroup analysis?

• Subgroup
  – A subset of people drawn from a larger group
    • Ex. Race, Ethnicity, Age, Sex

• Subgroup Analysis
  – Analyzing safety and effectiveness information separately for a subset of people
Why does subgroup analysis matter?

• Improves our understanding of diseases
  – Examine race, sex and age
• Makes sure treatments and medical devices are safe and effective for all
• Women, people of color and elderly are underrepresented in clinical trials.
• “One size fits all” approach fails
One Dose Doesn’t Fit All

• FDA approved Ambien to treat insomnia.

• Millions take Ambien

• Many were involved in car accidents the next day due to drowsiness.
One Dose Fits All Fails

• Studies show Ambien stays in women’s bodies longer than in men.
• Women more likely to be impaired the next morning than men.
  – More likely to drive impaired
• So FDA reduced Ambien dosage for women 20+ years after approval.
Lesson Learned

• One dose does not fit all
• FDA should ensure the safety and effectiveness of treatments for everyone.
  – FDA failed
• Treatments should be proven safe and effective for all.
  – That requires studying subgroups
How Treatment Results Differ by Race, Sex and Age

• Break into small groups for activity and discussion