

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