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JOHNS HOPKINS  
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## Section B

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### Types of Trials

# Types of Trials: Clinical

- Retrospective
  - Case-control trial

# Types of Trials: Clinical

- Prospective
  - Historical control
  - Natural history trial

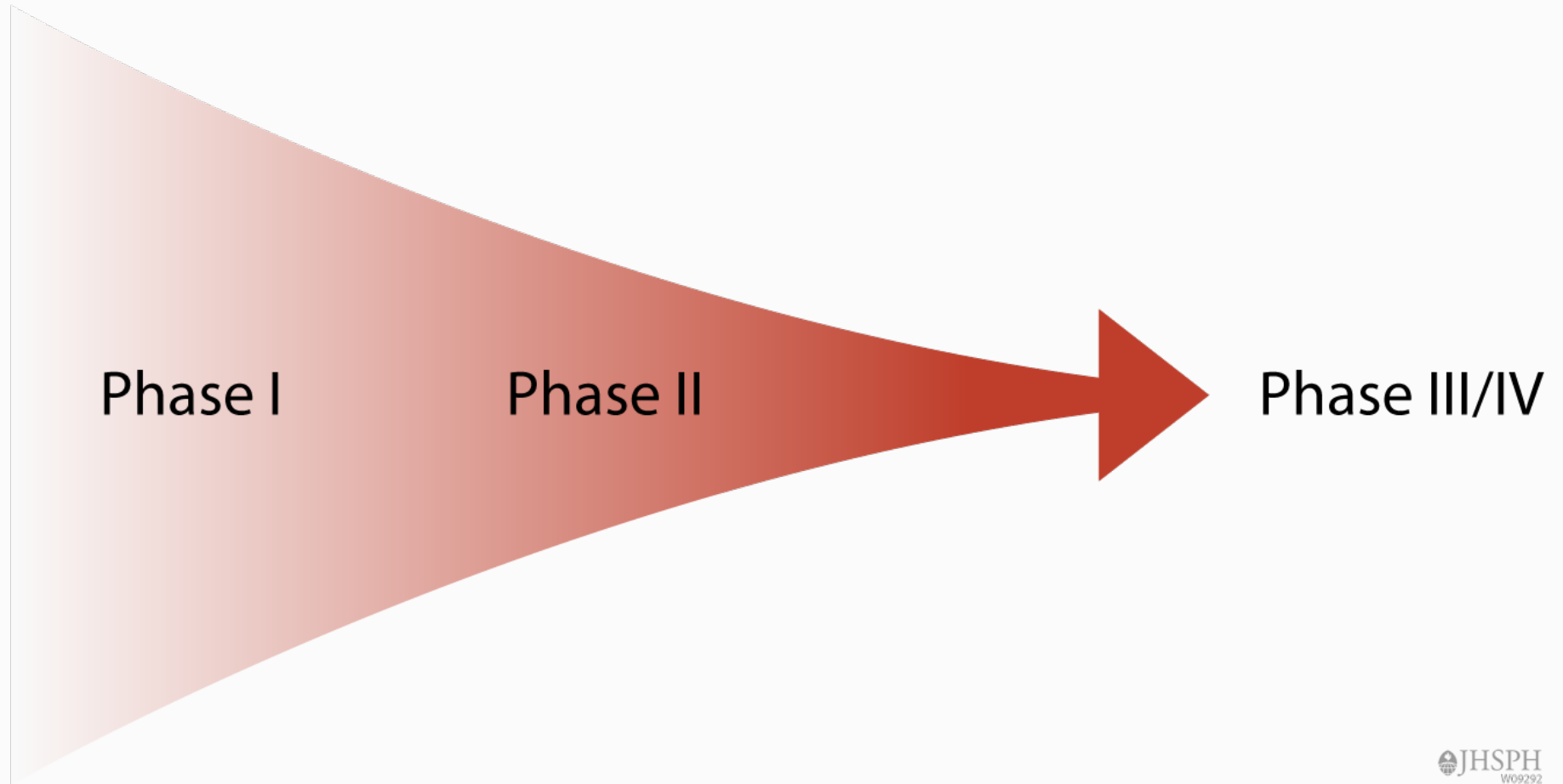
# Types of Trials: Clinical

- Prospective
  - Clinical trial
    - ▶ Equivalency/non-inferiority trial
    - ▶ Non-randomized controlled trial
    - ▶ Randomized controlled trial

# Types of Trials

- Clinical trials
  - Phase I
  - Phase II
  - Phase III
  - Phase IV

# Types of Trials



# Types of Trials: Clinical

- Clinical trials
  - Phase I (n = 20-80)
    - ▶ First in human trial
    - ▶ Safety
    - ▶ Dosage
      - Maximum tolerated dose (MTD)



# Types of Trials: Clinical

- Clinical trials
  - Phase II (20-300)
    - ▶ First dose, one lower than MTD
    - ▶ Assess biologic effect
    - ▶ Adverse events

# Types of Trials: Clinical

- Clinical trials
  - Phase III (300-3000+)
    - ▶ Based on results of Phase II
    - ▶ Effectiveness
    - ▶ Safety
    - ▶ Risk/benefit for adoption in clinical practice
  - Phase IV
    - ▶ Post-marketing trial
    - ▶ Long-term safety

# Types of Trials: Clinical

- Randomized controlled trial
  - Indifference among community of clinicians
    - ▶ Equipoise
  - Controlled
  - Randomized
    - ▶ Placebo
    - ▶ Blinding

# Placebo

- Placebo

- What is it?

- ▶ Pill that looks just like the drug but doesn't contain any medicine



**Drug**



**Placebo**

- Why it is included in study?

- ▶ Want to find out if the real medicine works like they hope it does. Need to compare people who get the real medicine to those don't to see if the medicine works.

# Types of Trials: Clinical

- Randomized controlled trial
  - Randomized
    - ▶ Placebo
    - ▶ Blinding

# Types of Trials: Clinical

- Randomized controlled trial
  - Placebo or active control

# Types of Trials: Clinical

- Randomized controlled trial
  - Placebo or active control
    - ▶ Standard of care

# Types of Trials: Social and Behavioral

- Observation
  - Direct
  - Participant



# Types of Trials: Social and Behavioral

- Survey

# Types of Trials: Social and Behavioral

- Interviews
  - Individual
  - Group

# Types of Trials: Social and Behavioral

- Ethnography
  - Combination of methods