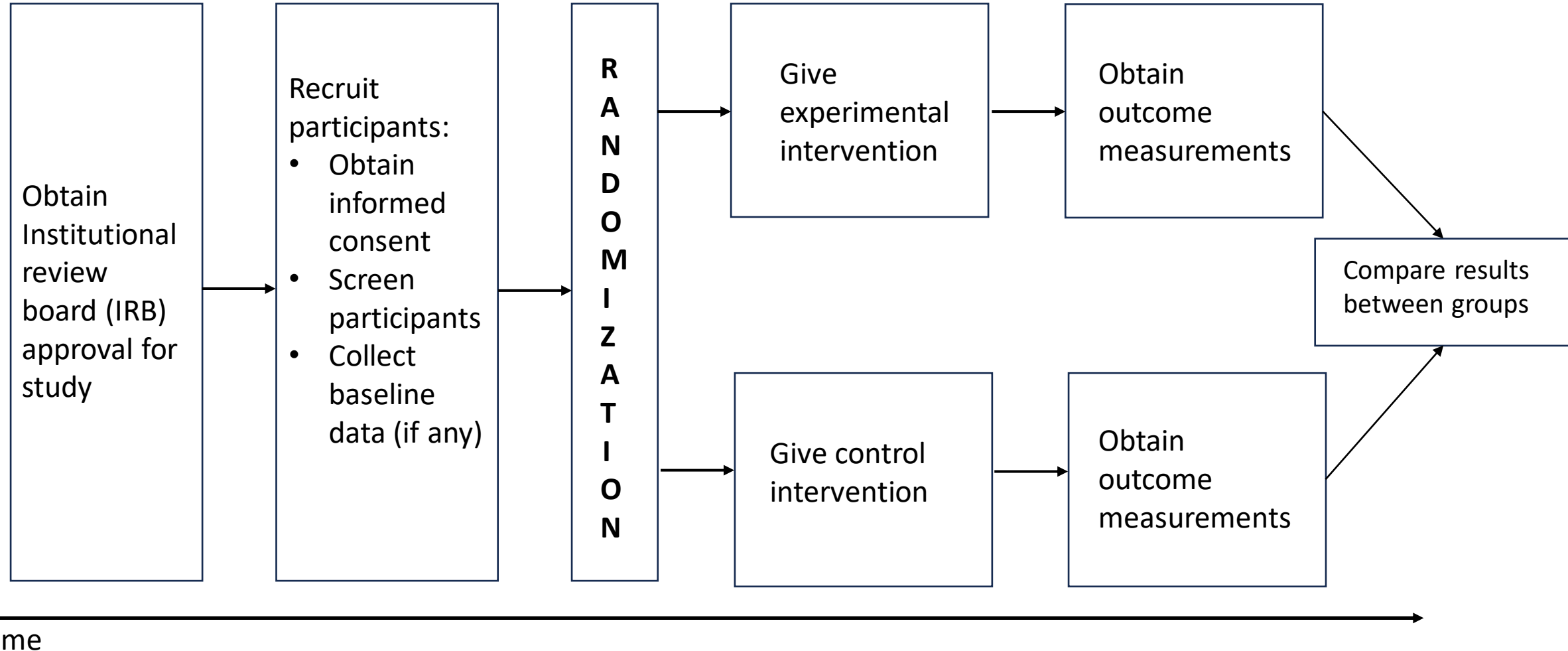


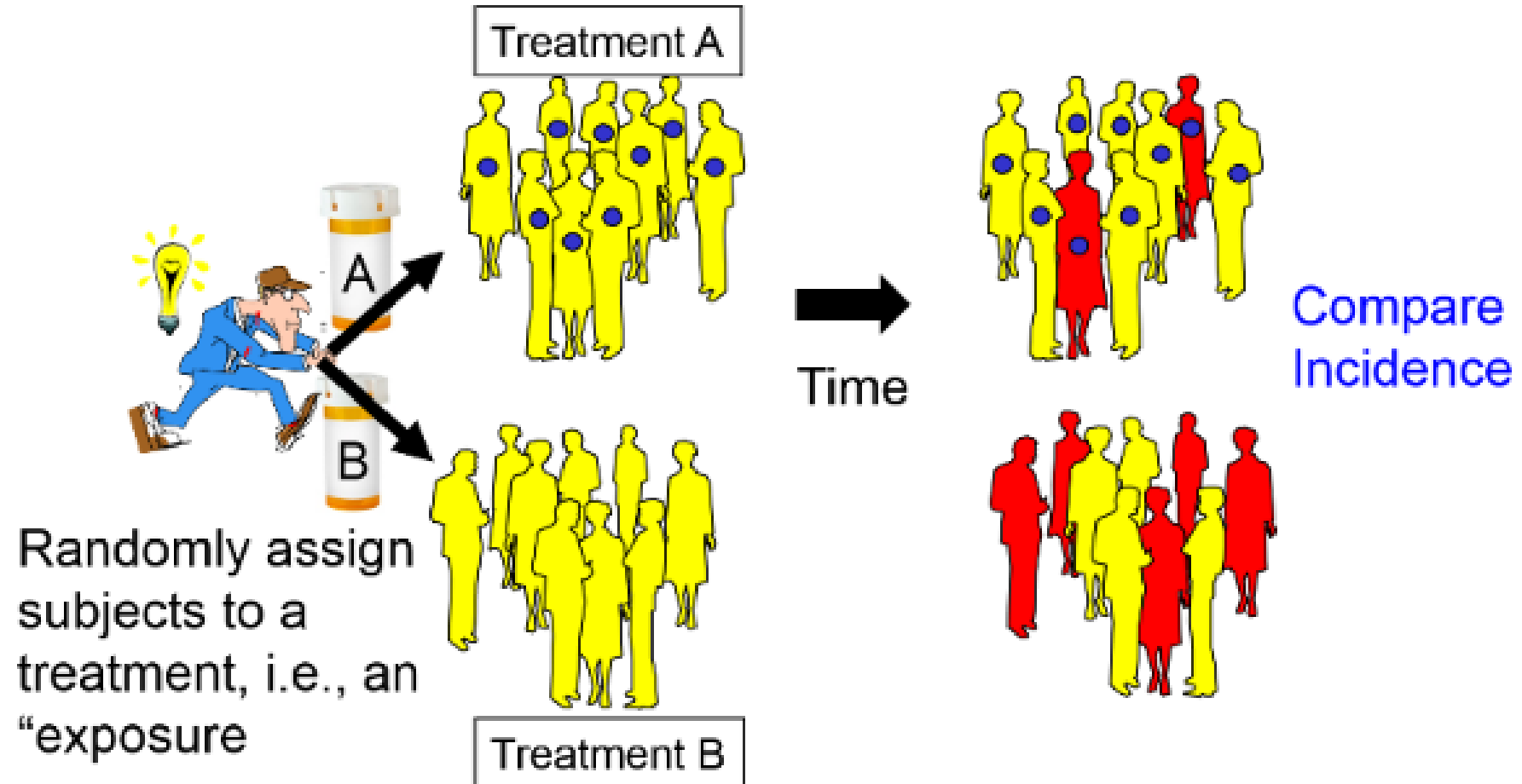
Methods of Research

Part Two

Interventional Studies



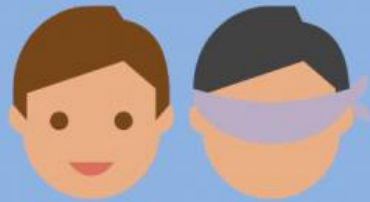
Concept of Randomization



Blinding

Single Blind vs Double Blind Study

Single Blind



Researcher knows treatment groups.

Double Blind

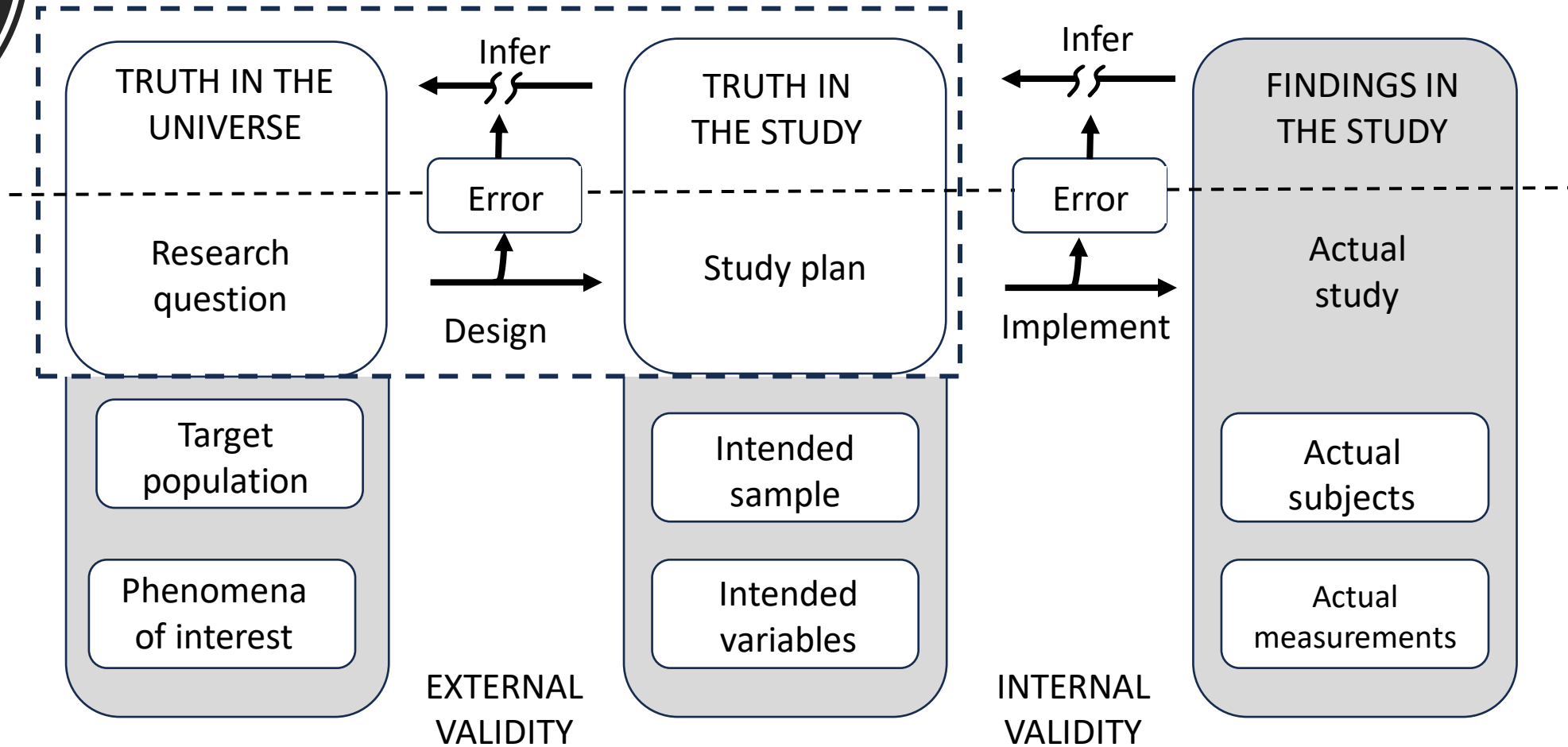


Neither researcher nor participants know treatment groups.



**What Could Possibly Go
Wrong?**

What Makes Clinical Research Difficult?



Sources of Error = Wrong Conclusions = Threats to Validity

- Sources of Error
 - Design
 - Study sample- inclusion and exclusion criteria
 - Power or sample size
 - Measures used in the study
 - Data management
 - Analysis of results
 - Interpretation of results

Errors in Design

- Study design does not match the question that the team is trying to answer
- The study is too short and ends before the outcome of interest occurs in most individuals

Errors in Study Sample

- Participants don't reflect the larger population of interest
- Participants will not respond to the study intervention

Errors in Sample Size

- Not enough participants enrolled to be able to detect a difference

Errors in Study Measures

- Measures phenomena of interest
- Responsive to the treatment
- Change during the duration of the study
- Reflect a clinically important change

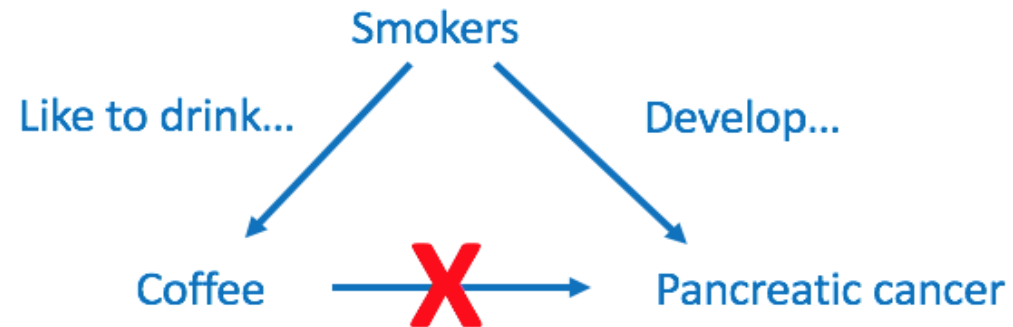
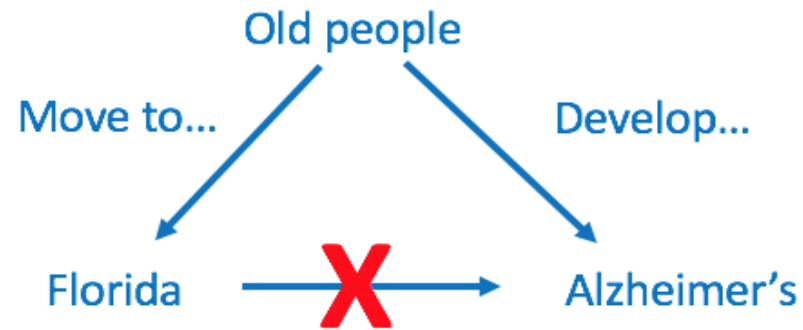
Does the outcome measure the phenomena of interest?



Is the Effect of the Intervention Clinically Meaningful?



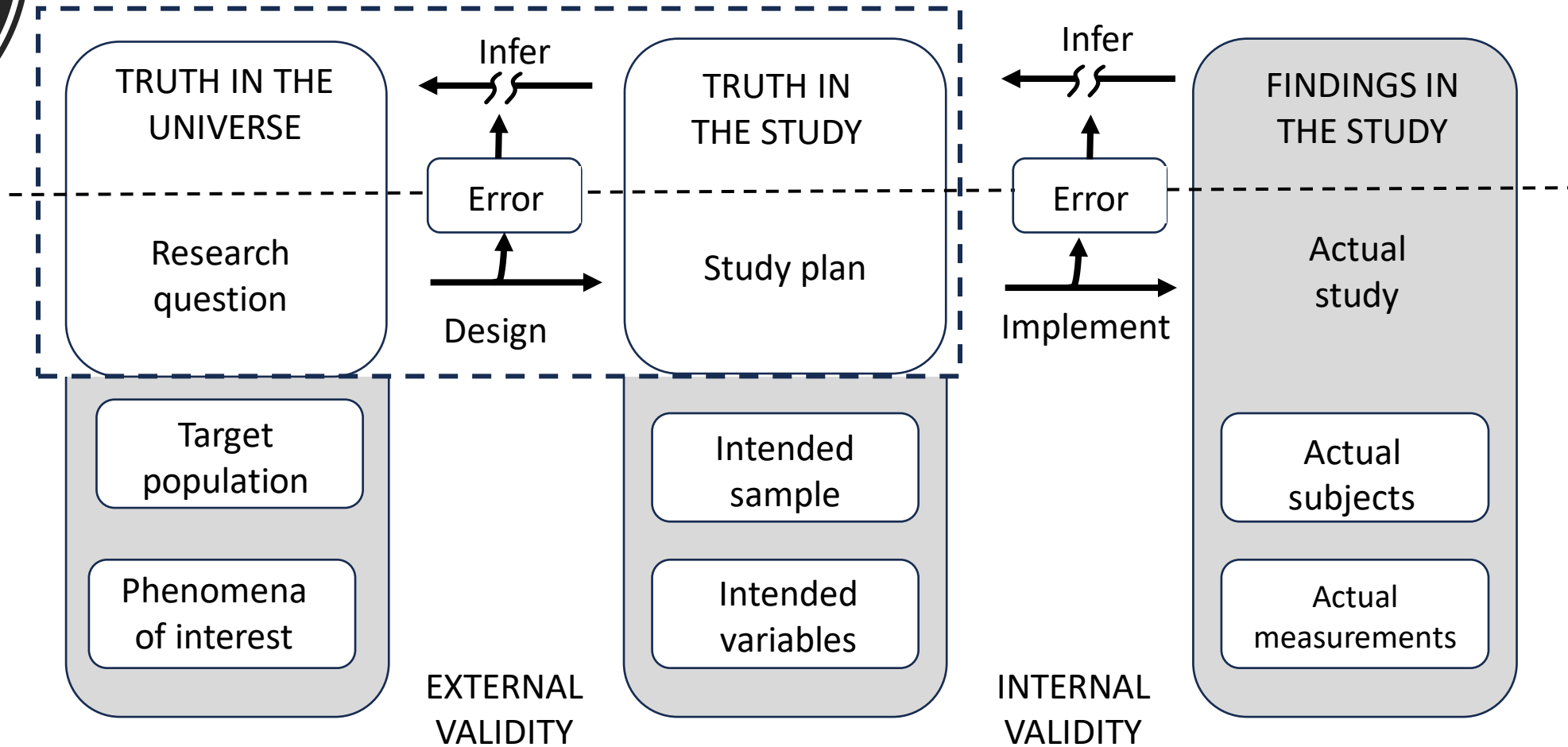
Confounding- Example of Incorrect Interpretation of Results



Errors in Data Management, Analysis, and Interpretation of Results

- Data collection is incomplete, challenging to analyze
- Incorrect analysis for the study design or outcome measures
- Results are interpreted incorrectly

What Makes Clinical Research Difficult?



Dissemination of Results

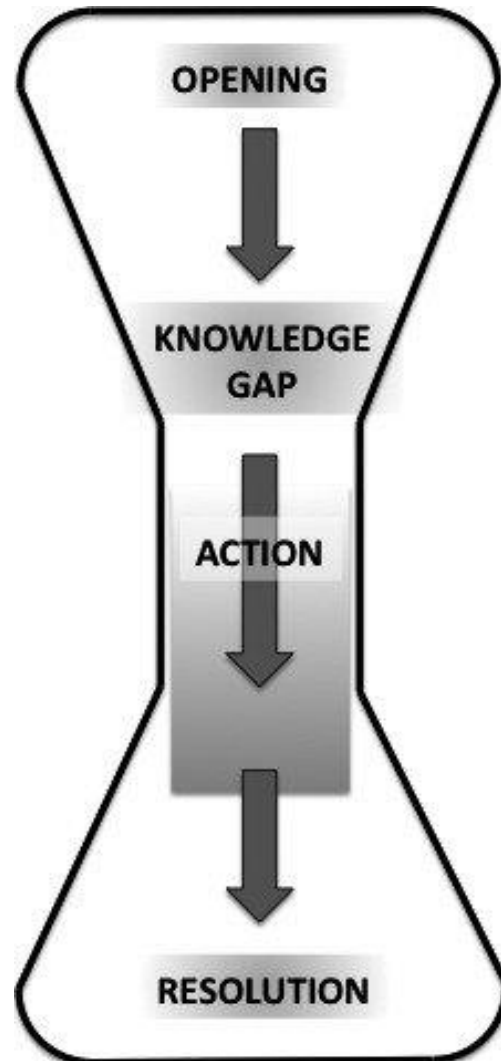
Importance of Publishing

- Disseminate research findings to advance scientific knowledge and improve human health
- Ethical mandate to make results available in a timely manner
- Maintain public trust in research transparency
- Enhance visibility of research
- Demonstrate credibility of work
- Measure of success
- Boost funding and promotion

What Is Peer Review?



Manuscript Structure



INTRODUCTION

*INTRODUCE RELEVANT LITERATURE
EXPLAIN WHY YOUR STUDY IS NOVEL
HYPOTHESIS*

MATERIALS AND METHODS

*INTRODUCE STUDY SYSTEM
EXPLAIN METHODS SUCH THAT A READER
COULD RECREATE YOUR STUDY*

RESULTS

*OBJECTIVELY STATE FINDINGS
FOCUS ON BIOLOGICAL RESULTS
USING STATISTICS FOR SUPPORT*

DISCUSSION

*INTERPRET YOUR RESULTS
TIE YOUR RESULTS BACK TO THE LITERATURE
BY ANSWERING THE KNOWLEDGE GAP*

CONCLUSIONS AND IMPLICATIONS