HOW TO APPLY THE MULTIPHASE OPTIMIZATION STRATEGY (MOST) IN YOUR INTERVENTION DEVELOPMENT RESEARCH

Module 5

Rigorous and responsible conduct of intervention optimization research

Lesson 6: Equipoise in optimization trials

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In the previous lesson you learned how to:

- Enter an optimization trial into a clinical trials registry (such as ClinicalTrials.gov in the US)

In this lesson you will learn how to:

- Generalize the concept of clinical equipoise to an optimization trial

What is equipoise?

- Freedman (1987):
  - Clinical equipoise exists “if there is genuine uncertainty within the expert medical community—not necessarily on the part of the individual investigator—about the preferred treatment.” (p. 141)
- The INVESTIGATOR may believe that the experimental treatment is preferred
- But what matters is the body of scientific evidence

Equipoise in an RCT

- In a 2-arm RCT, clinical equipoise means…

- …there is not a convincing body of scientific evidence supporting the idea that either the experimental treatment or the comparator treatment is preferred

Equipoise in an optimization trial

- An optimization trial has >> 2 experimental conditions
- These represent different versions of a treatment
- Clinical equipoise exists if there is no scientific consensus about which of these is preferred over the others

Equipoise in an optimization trial

- Remember, this is NOT about what YOU (as the investigator) believe
- It is also not about what theory predicts
- It is about what the **empirical scientific evidence** to date demonstrates
- If there is no scientific evidence, then there is no evidence that any treatment is preferred

How to approach equipoise in a factorial optimization trial

- Start by reviewing all the main effects. Is the null hypothesis scientifically plausible in each case?
- Then review the interactions. Again, is the null hypothesis scientifically plausible?
- OR you can review the list of experimental conditions

In this lesson you learned how to:

- Generalize the concept of clinical equipoise to an optimization trial

In the next lesson you will learn how to:

- Avoid accidental contamination between experimental conditions

References Cited

- Freedman, B. (1987). Equipoise and the ethics of clinical research. *New England Journal of Medicine*, *317*, 141-145.