



May 12, 2025

Comparing Drug Benefit to Overall Harm Using a Concept of Demonstrated Insusceptibility to Treatment

In larger randomized clinical trials, such as Phase III and Phase IV trials, data on adverse events is collected to determine if a purported benefit of a treatment outweighs the risk of the treatment in the intended population. However, a sample size is typically selected which is too small to rule out an increase in serious harms. Benefit is thus compared to harm using a hypothesis test for the beneficial outcome, versus an underpowered, sometimes informal assessment of possible treatment harm.

Learning Objectives:

- Explain how large randomized clinical trials (RCT) are currently failing in their purpose of determining if there is evidence for treatment benefit which outweighs evidence for possible harm
- Propose a method of analysis of demonstrated insusceptibility to treatment which might better serve this purpose

Presenter

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C2E2 Spotlight is held monthly on Mondays from 12:00 pm to 1:00 pm. To attend in-person or virtually please contact pamela.lee@ubc.ca.