

University of Washington Department of Biostatistics
2024 Summer Institute in Statistics for Clinical & Epidemiological Research
Module 6: Topics In Clinical Trials: Issues in Non-Inferiority Trials and
Addressing Missing Data

Thomas Fleming, University of Washington Professor of Biostatistics and Statistics and
Module 6 Instructor

Times listed are PDT (Seattle time; GMT-7). We will take one 30-minute break.

Monday, July 15th, 2024

8:30-10:00am **Session 1: Addressing Missing Data**

- A. Factors contributing to Missing Data
- B. Approaches to Addressing Missingness
- C. Inherent Limitations of Approaches for Treating Missing Data
- D. The Successful Prevention of Missing Data: Illustrations and Conclusions

- Fleming TR. Addressing Missing Data in Clinical Trials. *Annals of Internal Medicine* 154: 113-117, 2011.

- National Research Council. The Prevention and Treatment of Missing Data in Clinical Trials. Panel on Handling Missing Data in Clinical Trials. Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC: National Academies Pr; 2010.

10:00-10:30am Break

10:30-Noon **Session 2: Issues in Non-Inferiority Trials**

- A. Motivating the Proper Role of Non-Inferiority Trials
- B. The Constancy Assumption: Recognizing its Importance and Addressing Uncertainty about its Validity
- C. Determining the Non-Inferiority Margin
- D. Illustrating the Successful Design and Conduct of Non-Inferiority Trials

- Fleming TR, Odem-Davis K, Rothmann MD, Shen YL. Some Essential Considerations in the Design and Conduct of Non-Inferiority Trials. *Clinical Trials* 8:432-439, 2011.

1. Zoom polls are anonymous.
2. Please mute your microphone unless you are speaking.
3. Please sign into the Zoom session using the name used for registration, as access is restricted to module registrants.
4. Course materials and session link are posted on the SISCER Module 6 page (access for module registrants only).
5. A Slack channel for Module 6 in the SISCER Slack workspace is available for discussion and questions outside of live lectures.
6. After the module, please provide feedback using the module evaluation through your Summer Institutes account. After you complete the evaluation, you will be able to download a certificate of completion for this module.