

Non-Inferiority Trials

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References

1. Kaul S, Diamond GA. Good enough: a primer on the analysis and interpretation of noninferiority trials. *Ann Intern Med*. 2006;145(1):62-69. doi:10.7326/0003-4819-145-1-200607040-00011
2. Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJW, CONSORT Group. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. *JAMA*. 2006;295(10):1152-1160. doi:10.1001/jama.295.10.1152
3. Fleming TR. Current issues in non-inferiority trials. *Stat Med*. 2008;27(3):317-332. doi:10.1002/sim.2855
4. Schumi J, Wittes JT. Through the looking glass: understanding non-inferiority. *Trials*. 2011;12:106. doi:10.1186/1745-6215-12-106
5. Mulla SM, Scott IA, Jackevicius CA, You JJ, Guyatt GH. How to use a noninferiority trial: users' guides to the medical literature. *JAMA*. 2012;308(24):2605-2611. doi:10.1001/2012.jama.11235
6. Research C for DE and. Non-Inferiority Clinical Trials. U.S. Food and Drug Administration. Published April 27, 2020. Accessed January 25, 2022. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/non-inferiority-clinical-trials>
7. Rothmann M, Li N, Chen G, Chi GYH, Temple R, Tsou HH. Design and analysis of non-inferiority mortality trials in oncology. *Stat Med*. 2003;22(2):239-264. doi:10.1002/sim.1400
8. D'Agostino RB, Massaro JM, Sullivan LM. Non-inferiority trials: design concepts and issues - the encounters of academic consultants in statistics. *Stat Med*. 2003;22(2):169-186. doi:10.1002/sim.1425
9. Food and Drug Administration, HHS. International Conference on Harmonisation; choice of control group and related issues in clinical trials; availability. Notice. *Fed Regist*. 2001;66(93):24390-24391.
10. Effects of recombinant hirudin (lepirudin) compared with heparin on death, myocardial infarction, refractory angina, and revascularisation procedures in patients with acute myocardial ischaemia without ST elevation: a randomised trial. Organisation to Assess Strategies for Ischemic Syndromes (OASIS-2) Investigators. *Lancet*. 1999;353(9151):429-438.
11. FDA Oncology Drugs Advisory Committee Briefing Document. NDA 21-677. Alimta as Single Agent is Indicated for Treatment of Patients with Locally Advanced or Metastatic Non-small Cell Lung Cancer (NSCLC) After Prior Chemotherapy. Eli Lilly and Company, 27 July 2004. www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4060b1.htm
12. Patel MR, Mahaffey KW, Garg J, et al. Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation. *New England Journal of Medicine*. 2011;365(10):883-891. doi:10.1056/NEJMoa1009638
13. Willenheimer R, van Veldhuisen DJ, Silke B, et al. Effect on survival and hospitalization of initiating treatment for chronic heart failure with bisoprolol followed by enalapril, as compared with the opposite sequence: results of the randomized Cardiac Insufficiency Bisoprolol Study (CIBIS) III. *Circulation*. 2005;112(16):2426-2435. doi:10.1161/CIRCULATIONAHA.105.582320