SISCER 2020 Module 9

Data Monitoring Committees and Statistical Data Analysis Centers:

Guiding Principles and Best Practices

Additional Articles:

Buhr K, Downs M, Rhorer J, Bechhofer R, Wittes J (2018). Reports to Independent Data Monitoring Committees: An Appeal for Clarity, Completeness, and Comprehensibility. Ther Innov Reg Science 52:459-468.

DeMets DL, Ellenberg SS. Data Monitoring Committees - Expect the Unexpected. N Engl J Med. 2016;375(14):1365-1371. doi:10.1056/NEJMra1510066

DeMets DL, Pocock SJ, Julian DG. The agonising negative trend in monitoring of clinical trials. Lancet. 1999;354(9194):1983-1988. doi:10.1016/S0140-6736(99)03464-9

Ellenberg SS, Culbertson R, Gillen DL, Goodman S, Schrandt S, Zirkle M. Data monitoring committees for pragmatic clinical trials. Clin Trials. 2015;12(5):530-536. doi:10.1177/1740774515597697

Fleming TR, DeMets DL, Roe MT, et al. Data monitoring committees: Promoting best practices to address emerging challenges. Clin Trials. 2017;14(2):115-123. doi:10.1177/1740774516688915

Fleming TR, Ellenberg SS, DeMets DL. Data Monitoring Committees: Current issues. Clin Trials. 2018;15(4):321-328. doi:10.1177/1740774518764855

Neaton JD, Grund B, Wentworth D (2018). How to construct an optimal interim report: What the data monitoring committee does and doesn’t need to know. Clinical Trials 5: 359-365

Wittes J, Shactman M (2014). On independent data monitoring committees in oncology clinical trials. Chinese Clinical Oncology 3: Sept .

Wittes J, Barrett-Connor E, Braunwald E, et al. Monitoring the randomized trials of the Women's Health Initiative: the experience of the Data and Safety Monitoring Board. Clin Trials. 2007;4(3):218-234. doi:10.1177/1740774507079439

Books:

Ellenberg, Fleming, DeMets, Data Monitoring Committees in Clinical Trials: A Practical Perspective (2nd edition, Wiley, 2019)

Herson J. Data and Safety Monitoring Committees in Clinical Trials, second edition. Chapman and Hall 2016.

DeMets, Furberg, Friedman, Data Monitoring Committees in Clinical Trials: A Case Studies Approach, Springer 2006