Stopping Rules and Data Monitoring in Clinical Trials

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Abstract

Philosophers subscribing to particular principles of statistical inference need to be aware of the limitations and practical consequences of the statistical approach they endorse. The framework here proposed, together with methodological guidelines, allows disparate statistical approaches to emerge in their appropriate context while providing important considerations for deciding on trial conduct. While these considerations do not amount to stopping rules, they would assist data monitoring committees in judging their position with regard to necessary precautionary interpretation of interim data. My conclusion raises suspicions about philosophies of science that promote a universal principle of statistical inference applied to clinical trials.

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