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# Statistical Decisions and the Interim Analyses of Clinical Trials

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## Abstract

This paper analyzes statistical decisions during the interim analyses of clinical trials. After some general remarks about the ethical and scientific demands of clinical trials, I introduce the notion of a hard-case clinical trial, explain the basic idea behind it, and give a real example involving the interim analyses of zidovudine in asymptomatic HIV-infected patients. The example leads us to a proposed decision analytic framework for handling ethical conflicts that might occur during the statistical monitoring of hard-case clinical trials. I use computer simulations to show how the framework can assist in reconciling certain ethical conflicts. The framework proposed is partial, and lacks the precision of a complete systematization of statistical monitoring procedures in practice.

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