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**A Survival Analysis Instead of an Endpoint Analysis for
Antibiotic Data**

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Abstract

Phase II or Phase III clinical trials of new antibiotic compounds are usually positive controlled with two treatments: the new antibiotic compound versus an already marketed compound, and incorporate a randomized parallel design. Patients are on treatment for a specified period, are seen at various times during the period, and are seen at least once following the cessation of treatment. The efficacy variable is cure, microbiological and/or clinical. A clinical cure, for example, is typically defined as a complete abatement of signs and symptoms of the infection by the end of treatment and at the first post-treatment follow-up. Analyses of efficacy data are usually restricted to endpoint analyses of the proportions of patients cured. These analyses ignore the time of cure. Survival data or time-to-event analysis methods would, however, incorporate both the cure and the time at which it occurred. In a prospective sense, survival analyses of the efficacy data do not apply since it is not possible to classify a patient as cured or not cured during the treatment period. Retrospectively, however, a patient may be so classified and the "cure" located where it occurred. Survival analysis methods, the Mantel-Haenszel Procedure, for example, may then be applied treating time to cure as response, to test the hypothesis of no treatment difference. Withdrawals from the trial may also be incorporated in the analysis.

Keywords: *Antibiotic Clinical Trials, Endpoint Analysis, Survival Analysis*