Reviewer's report

Title: A Comparison of a New Multinomial Stopping Rule with Stopping Rules of Fleming and Gehan in Phase II Cancer Clinical Trials

Version: 1 Date: 19 January 2011

Reviewer: Junfeng Liu

Reviewer's report:

Summary of authors' contributions

Multinomial stopping rules which assume a trinomial distribution among a number of patients with three states (response, early disease progression, nothing) are developed by Zee et al (1999). The related study and modifications are given by Dent et al (2001), Goffin and Tu (2008) and Tan et al (2010). An analogous method for handling (partial, complete) response is by Panageas et al (2002). This manuscript compares the approach by Goffin and Tu (2008) with representative single endpoint (response) approaches (Gehan 1961, Fleming 1982).

[1] Major compulsory revisions:

The specific two sets of parameters may not give a global picture on the operating characteristics profile. Reader-friendly results can be presented using plots with varying parameter values (e.g., ralt, rmul; epdalt, epdnul) under each two-stage design configuration (n1r,n1p;n2r,n2p). The relationship (monotone or not) between true parameters and "alpha, beta" error rates can be displayed.

[2] Discretionary revisions:

Comparison among multiple approaches may need be done under a common criterion (e.g., what type of cost-effectiveness measurement from medical decision point of view?). Is it possible to consider the bivariate endpoint (each patient carries a pair of records: response and early disease response) based design?

[3] Minor essential revisions:

Does "efficient" mean "specific" in line 7 (Section: Background)? "when drug is inactive" may be needed behind "minimize the expected number of enrolled patients" (paragraph 2, Section: Background).

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable
**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.