A New Scheme to Estimate Median Progression-free Survival Time in Oncology Clinical Trials

Peng Li, Xing Sun, Cong Chen and Anderson Keaven *

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Abstract

Progression-free survival (PFS) has been accepted as a valid primary endpoint in many previous anti-tumor therapeutic product marketing approvals. Yet, it has been long known that current standard statistical methods to handle PFS data widely adopted in pharmaceutical industry may lead to serious bias under certain circumstances. Although most statistical issues related to two or multiple treatment group comparison problem for PFS data can be resolved, the challenge to provide a practical and better median PFS estimation still remains, which is an even more important question to address in order to get a thorough understanding of the treatment effect in everyday medical practice. In this paper, the author proposes a simple alternative trial design idea together with a new estimation scheme to solve this issue. The performance of the new method based on this new scheme will be compared to the standard method currently used by the pharmaceutical industry via simulations under typical oncology study settings.

Keywords: survival analysis, interval censor, progression-free survival, Kaplan-Meier, NPMLE

*Peng Li and Xing Sun are with Sanofi & Co., Inc., 5F, No. 112 Jian Guo Lu, Beijing, China, 100022. Email: peng.li, xing.sun@sanofi.com. Cong Chen and Anderson Keaven are with Merck & Co., Inc., 351 N Sumneytown Pike, North Wales, PA, 19454, US. Email: cong_chen, anderson_keaven@merck.com.