

Clinical Trial Design Systems

A Brief manual for CTDSystems

- In Design Settings, Confidence Limit (%) is to specify the confidence limit for confidence intervals.
- In Confidence Interval, Lower Limit of UMVUE and Upper Limit of UMVUE are the limits of Jennison-Turnbull confidence intervals.
- The CI method based on MLE ordering is not published yet. MLE-CIs are obtained like UMVUE-CIs, but based on different orderings, MLE vs. UMVUE.
- Basic requirement for CTDSystems Applet: Java(TM) 2 Runtime Environment, Standard Edition 1.4.2 or 1.5
- Please send emails to sinho.jung@duke.edu for any questions and comments about CTDSystems.
- This program, CTDSystems, has gone through a thorough validation procedure. However, we cannot guarantee that it is 100% error free yet. Please use our program at your own risk.

For analysis of two-stage phase II trials, users may refer to

- Simon R. Optimal two-stage designs for phase II clinical trials. *Control Clin Trials* 1989; 10: 1-10.
- Jung SH, Carey M and Kim KM. Graphical search for two-stage phase II clinical trials, *Controlled Clinical Trials* 2001; 22: 367-372.
- Jung SH, Lee TY, Kim KM, George S. Admissible two-stage designs for phase II cancer clinical trials, *Stat Med* 2004; 23: 561-569.

- (For 'Apply both boundaries' option, refer to) - Chen TT. Optimal three-stage designs for phase II cancer clinical trials. Stat Med 1997; 16: 2701-2711.

For analysis of two-stage phase II trials, users may refer to

Estimation of response rate

- Jung SH, Kim KM. On the estimation of the binomial probability in multistage clinical trials, Stat Med 2004; 23: 881-896.

Confidence interval of response rate

- Jennison C, Turnbull BW. Confidence intervals for a binomial parameter following a multistage test with application to MIL-STD 105D and medical trials. Technometrics 1983; 25:49-58.
- Jung SH, Kim KM. On the estimation of the binomial probability in multistage clinical trials, Stat Med 2004; 23: 881-896.

P-value

- Jung SH, Owzar K, George SL, Lee TY. P-value calculation for multistage phase II cancer clinical trials (with discussion), J Biopharmaceutical Statistics 2006; 16: 765-783.