

Gating criteria using Bayesian approach in early phase study

Wenxin Liu

Roche China

E-mail: wenxin.liu@roche.com

Abstract: This presentation will introduce the gating criteria using Bayesian approach in early phase study.

Usually gating criteria is prespecified before readout of a small sample size of patients' data. Based on the prespecified gating criteria, the sponsor can develop decision making strategy, including Pivotal Go, Go, No Go. In this presentation, a binary endpoint ORR is considered.