

Proof of Concept Decision Making in Phase 1b Cohort Expansion Study

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Abstract: Single-arm cohort expansion studies are increasingly used as proof-of-concept (POC) studies for immunotherapies as compared to conventional randomized POC studies. We proposed a Bayesian three-tier framework to facilitate quantitative decision making in early phase clinical development programs which potentially could better balance between development speed and uncertainties. Characteristics of the framework were evaluated via simulations and we compared our framework with other available frameworks.