# INNOVATIVE TRIAL DESIGNS ARE PRACTICAL SOLUTIONS FOR IMPROVING THE TREATMENT OF TUBERCULOSIS

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A growing number of new drugs for the treatment of tuberculosis are in clinical development. Confirmatory phase 3 trials are expensive and time-consuming and the question of whether one particular drug combination can be used to treat tuberculosis is less important from a public health perspective than the question of which are the shortest, simplest, most effective, and safest regimens. While preclinical and phase 1 studies provide some guidance in the selection of combinations for clinical evaluation, a large number of combinations will require phase 2 testing to ensure that only the best regimens advance to phase 3. The multi-arm multi-stage trial design is an example of a treatment selection–adaptive design where multiple experimental arms are each simultaneously compared with a common control and interim analyses allow for poor performing arms to be dropped early. Such designs, if designed and implemented correctly, require fewer patients, can be completed in a shorter time frame, and answer more relevant questions without any loss in statistical validity or scientific integrity. There are, however, practical issues that must be considered in applying this in tuberculosis treatment trials. More innovative trials designs should be considered to speed drug and regimen development for the treatment of tuberculosis.