

**A BAYESIAN APPROACH FOR INFERENCE FROM A BRIDGING STUDY WITH BINARY OUTCOMES**

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A clinical trial is an experiment testing a medical treatment or intervention on human subjects. Clinical trials require a carefully planned combination of clinical and statistical reasoning to provide confirmatory evidence of treatment effect. Clinical trials are required before a national regulatory authority will approve marketing of a drug for use on patients. However, to address concerns that ethnic differences may affect the medication's safety, efficacy, dosage and dose regimen for different patient populations, separate clinical trials may be required for different parts of the world. If the drug is approved in one region based on trial(s) conducted on a large number of subjects, usually a bridging study with a relatively small sample size is conducted in a new region to evaluate the similarity for extrapolation of the foreign clinical data to the patient population of the new region. In this paper we propose a Bayesian approach to combine the data generated by a bridging study and a reference study for assessment of similarity based on treatment effect. This method incorporates input from clinical, regulatory and statistical perspectives. The method is illustrated with an example.