

TITLE: Bayesian Supplemental Analysis Demonstration Project

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ABSTRACT:

The CDER Center for Clinical Trial Innovation (C3TI) aims to increase experience in Bayesian statistical methods in simple trial settings across sponsors, CDER clinical reviewers, and CDER statisticians, including deepening an understanding of their applicability, opportunities, and challenges. With the Bayesian Supplemental Analysis demonstration project, C3TI will partner with sponsors to integrate Bayesian analysis in parallel to frequentist analysis for their clinical trials. This allows an opportunity to learn new methods without impacting review criteria. Increasing the experience and understanding of Bayesian approaches in an experiment-friendly environment may facilitate their use as primary analyses in appropriate future settings