**TITLE: My experience with Bayesian pediatric extrapolation as a statistical reviewer**

**Author:** Wenda Tu, *CDER/FDA*

**Abstract:**

The application of Bayesian borrowing methods in pediatric clinical trials offers a promising pathway to alleviate the common challenges posed in a pediatric drug development program (e.g., ethical concerns, financial constraints, and recruitment difficulties, etc.). By incorporating prior information from adult and/or historical pediatric data in the analysis of concurrent pediatric data, Bayesian pediatric extrapolation efficiently reduces the trial sample size and expedites the availability of new therapies for children. In this session, we will examine the application of Bayesian pediatric extrapolation in a regulatory setting. We will cover the regulatory guidance (e.g., ICH E11A) on pediatric extrapolation, the common Bayesian methods used for pediatric trial design and analyses, and the caveats for Bayesian pediatric borrowing. A wealth of case studies (consisting of recent NDA/BLA reviews on pediatric studies involving Bayesian extrapolation) will be supplied to vividly demonstrate how the appropriateness and strength of borrowing, in conjunction with the evidence collected from concurrent trial data, have led to various regulatory actions for pediatric drug approval.