

**Indiana University-Purdue University
Indianapolis**
Department of Mathematical Sciences

STATISTICS SEMINAR

12:15pm—1:15pm, Tuesday, August 22, 2023
Zoom Meeting: Meeting ID: 845 0989 4694

Speaker: **Yishan Cui**
Department of Mathematical Sciences, IUPUI

Title: **Model based prediction of overall survival based on interim tumor assessment data in clinical trials**

Abstract:

Overall survival (OS) is often used as the primary endpoint of oncology Phase 3 pivotal clinical trials to support the regulatory approval of a cancer treatment. OS data can take time to mature, but other efficacy endpoints, such as progression-free survival (PFS) or tumor response, are usually evaluated before OS. In this context, predicting survival outcomes at the time of analyzing these early efficacy endpoints is of interest in guiding decision-making in the trial (e.g., early stop for futility on OS) and projecting strategic plans (e.g., starting new trials in different lines of treatment/indications). Currently, statistical methods for significance testing, incorporating partially observed interim data, are limited. In this project, we assess the use of Bayesian modeling approaches to predict survival outcomes with interim PFS data as a covariate to estimate the success probability of the trial. This method could benefit Sanofi trials and projects by enabling more informed decisions based on a quantitative assessment of tumor assessment data.