

*Symposium Program on Dose Selection for Cancer Treatments: May 12, 2017*

Speaker: Eric Polley, Ph.D.  
Assistant Professor of Biostatistics, Mayo Clinic

Title: Basket and Umbrella Trial Designs in Oncology

Abstract:

Improvements in molecular diagnostic assays, in particular high throughput sequencing assays, have allowed better characterizations of somatic alterations present in tumors. A central concept in oncology precision medicine is that the utilization of the genomic alterations can improve clinical outcomes by better matching treatments with these molecular biomarkers. The concept presents a change in oncology drug development and how clinical trials are designed. One new design is the Basket study design, where all patients have the same biomarker, but the study enrolls multiple cancer types. Another new design is the umbrella study design, where patients are screened upfront for multiple biomarkers and assigned to different sub-studies based on the results. These designs will be contrasted with traditional study designs and I will present areas where they can be extended to incorporate dose selection.