Challenges and Opportunities in Dose Optimization for Oncology Drug Development

BIOSTATISTICS SEMINAR

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Advancement of oncology and hematology drug development has brought many innovative medicines in recent years, such as immuno-therapies and CAR-T therapies. Several innovative statistical methods have also been used to help accelerated the drug development. Because of the enormous unmet medical need and severity of the disease burden, oncology drug development has traditionally focused on identifying the maximum tolerated dose (MTD) in phase I and moving quickly to phase III, sometimes utilizing a single arm trial at the MTD for accelerated approval. Recently, regulatory authorities have been emphasizing evaluation of the benefit risk in dose optimization and moving towards minimum effective dose (MED) before entering phase 3 development. In this presentation, we will discuss some challenges and opportunities in dose optimization for oncology drug development. In particular, we will discuss the idea of evaluating multiple doses in an inferential seamless phase II/III adaptive design to address dose optimization in pivotal trials. In addition, we will highlight a few statistical issues surrounding the role of biomarkers and quantitative measures of benefit and risk for selecting the optimal dose, multiplicity adjustment for dose selection in the final analysis of clinical outcomes based on combined data from both phases II and III, as well as maintaining blinding and trial integrity with adaptive designs.

Thursday March 31, 2022, 3:30-4:30 PM Eastern

McGavran-Greenberg Hall - Room 1301

Virtual using link and info below.

Link: https://unc.zoom.us/j/98412143955?pwd=a1p6c3hvZ28wSnk3dVVXQWl0dEpzdz09

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