BIOSTATISTICS SEMINAR

Assessment of Immune Marker Surrogate Endpoints in COVID-19 Vaccine Efficacy Trials: Pursuit through Multiple Causal Inference Approaches

Peter Gilbert, PhD
Biostatistics, Bioinformatics and Epidemiology Program
Vaccine and Infectious Disease and Public Health Science Divisions, Fred Hutch
Research Professor, Department of Biostatistics, University of Washington

Consider a phase 3 clinical trial that randomizes participants to active vs. control intervention, and follows participants for occurrence of a primary clinical endpoint. Suppose a candidate surrogate endpoint is measured at a fixed time point after randomization. Causal inference approaches to evaluating the candidate surrogate (e.g. a biomarker) include: (a) Principal Stratification to assess how the treatment effect on the clinical endpoint varies over subgroups defined by the counterfactual biomarker value if assigned active treatment; (b) Static Interventional Controlled Effects to assess controlled direct effects of assigning all participants to active vs. control and to a specific biomarker value; and (c) Stochastic Interventional Effects to assess the effect of assigning all participants to active vs. control and drawing the biomarker from specified distributions under each treatment. This talk will discuss how this set of causal approaches can be applied to understand how well – and how – the biomarker can be used for making inferences about the clinical treatment effect, with application to several COVID-19 vaccine efficacy trials conducted by the Coronavirus Prevention Network in public-private partnership with the vaccine developers. The talk focuses on the major application of a surrogate endpoint to transport/infer the clinical treatment effect in various contexts departing from the original phase 3 trial conditions.

Thursday November 10, 2022, 3:30-4:30 PM Eastern

133 Rosenau Hall

Virtual using link and info below.

Link: https://unc.zoom.us/j/92602267820?pwd=YW1wN1pjdUNVd1A4TTl2OStmVHBjQT09

Meeting ID: 926 0226 7820 Passcode: 533114

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