Statistical Evaluation of Immunological Markers in Vaccine Clinical Trials

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Abstract

One of important goals of vaccine development is to identify potential immunological markers that predict vaccine efficacy. Having such a predictive marker can substantially accelerate the vaccine development as subsequent studies can be conducted efficiently based on these immunological markers instead of efficacy endpoints. In this talk, we will present statistical approaches for assessing the predictive value of immunological markers. Methods based on the Prentice's criteria and a recently developed causal inference framework will be discussed. A real vaccine example will be used to illustrate the methods.

Keywords: Correlate of protection; Surrogate endpoints; Biomarkers.

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