# SURROGATE MARKERS - A PERSPECTIVE FROM REGULATORY ISSUES

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The talk will focus on the regulatory aspects of using surrogate markers in drug development. It will first cover the motivation and several working definitions. Next we explore the relationships of biomarkers and surrogate markers, and their unique roles in the drug development process. The main section will discuss in detail several regulatory issues related to surrogate markers such as accelerated approval and its unique statistical considerations. It will provide practical insight with regulatory experiences and case examples.