Clinical Trial Design to Access Rare Adverse Events

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For non-inferiority studies, the agreement for the choice of margin is a major step between the regulatory agency and the sponsor. In this talk, we consider the case where the event number is small for intermediate to large sample size studies. In practice, use of the constant margin for relative risk (RR) may cause some un-desirable characteristics for decision making. We will introduce another approach to this problem.

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