Statistical Methods for Immunogenicity Assessment (Chapman & Hall/CRC Biostatistics Series)

Harry Yang, Jianchun Zhang, Binbing Yu, Wei Zhao

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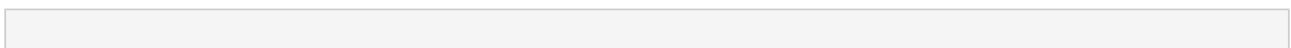
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Develop Effective Immunogenicity Risk Mitigation Strategies

Immunogenicity assessment is a prerequisite for the successful development of biopharmaceuticals, including safety and efficacy evaluation. Using advanced statistical methods in the study design and analysis stages is therefore essential to immunogenicity risk assessment and mitigation strategies. **Statistical Methods for Immunogenicity Assessment** provides a single source of information on statistical concepts, principles, methods, and strategies for detection, quantification, assessment, and control of immunogenicity.

The book first gives an overview of the impact of immunogenicity on biopharmaceutical development, regulatory requirements, and statistical methods and strategies used for immunogenicity detection, quantification, and risk assessment and mitigation. It then covers anti-drug antibody (ADA) assay development, optimization, validation, and transfer as well as the analysis of cut point, a key assay performance parameter in ADA assay development and validation. The authors illustrate how to apply statistical modeling approaches to establish associations between ADA and clinical outcomes, predict immunogenicity risk, and develop risk mitigation strategies. They also present various strategies for immunogenicity risk control. The book concludes with an explanation of the computer codes and algorithms of the statistical methods.

A critical issue in the development of biologics, immunogenicity can cause early termination or limited use of the products if not managed well. This book shows how to use robust statistical methods for detecting, quantifying, assessing, and mitigating immunogenicity risk. It is an invaluable resource for anyone involved in immunogenicity risk assessment and control in both non-clinical and clinical biopharmaceutical development.

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