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Universities

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Bachelors of Science

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Masters of Science, Report

Statistical analysis of bioassay data with dependent replicates

UNIVERSITY OF NEW BRUNSWICK

REPORT DEFENCE AND EXAMINATION

in Partial Fulfillment

of the Requirement for the Degree of
Master of Science

by

Liam J. Cann

in the Department of Mathematics & Statistics

U.N.B., Fredericton, N.B.

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Via MS TEAMS

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Abstract

Bioassays play a key role in ensuring that every batch of drug produced is safe and effective for release. They play a critical role in testing the potency of biologic drugs, such as vaccines or monoclonal antibodies. Due to the importance of bioassays in ensuring a safe and effective product, it is critical that the statistical methods used are appropriate. However, it is the current common practice to treat the replicate responses at each dose level as if they are independent despite the fact they are often correlated. In this research, we look at quantitatively assessing the risks of the conventional analysis methods using a simulation study to investigate the impact of correlation on the statistical analysis of bioassays. Specifically, we consider parallelism assessment, model goodness-of-fit, and relative potency estimation. We also make recommendations within the constraints of the current available commercial bioassay analysis software to provide valid statistical inference.

