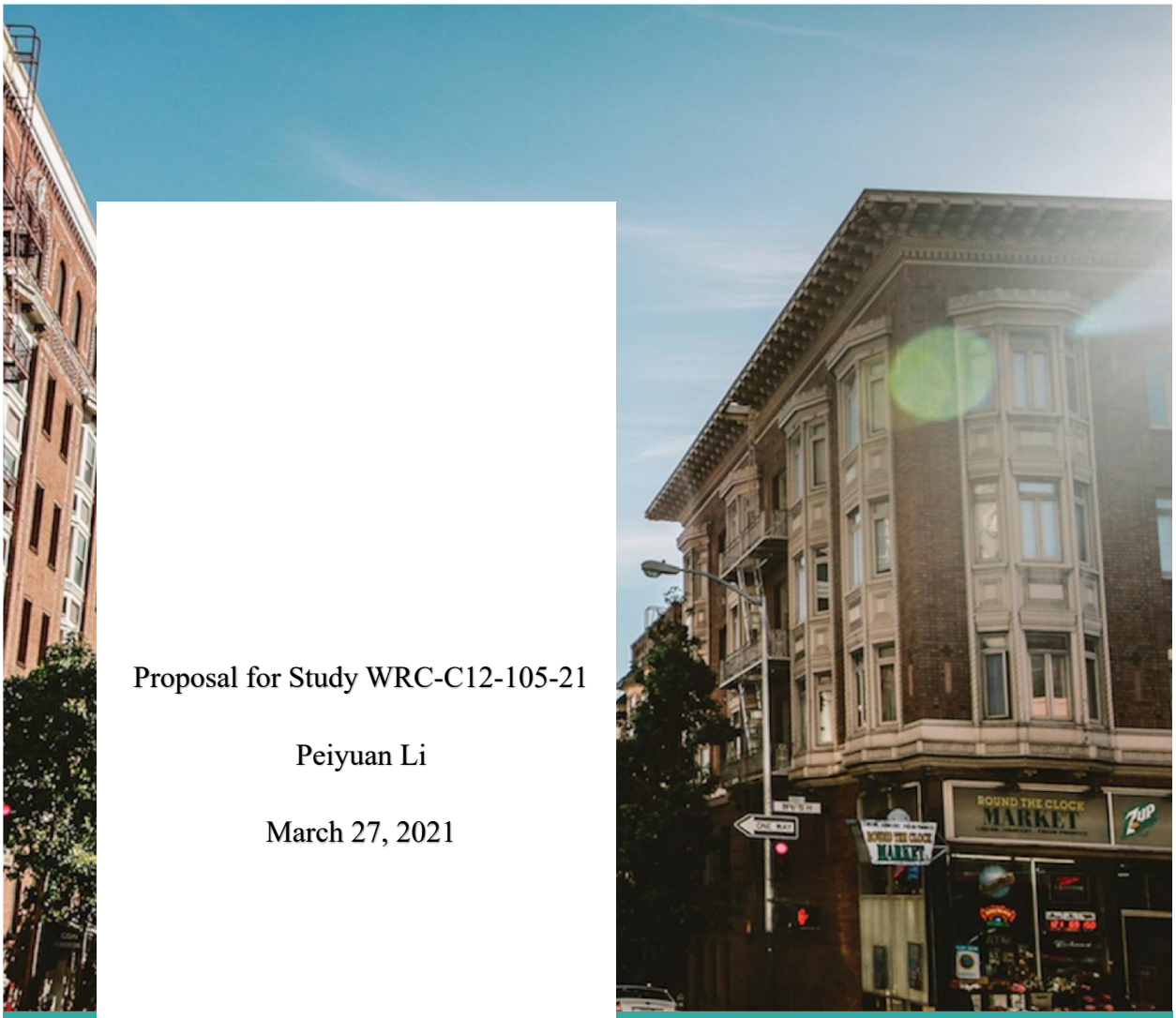

Proposal for Study WRC-C12-105-21

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Proposal for Study WRC-C12-105-21

This paper provides support for a study conducted by our client, WeRChicken, Inc. Based on the information gathered, we, Stat300 Consultants, Inc., has developed a statistical analysis plan to address some of our client's questions of interest.

Introduction

WeRChicken, Inc. conducted a series of studies to evaluate the efficacy of the Salmonella Enteritidis fraction of a combination vaccine against Salmonella enteric serovar Enteritidis (SE) in Chickens. We believe WRC-C12-105-21 is a causative study. The objective of this study is to show that client's vaccine prevents SE regardless of whether it is administered subcutaneously (SC) or intramuscularly (IM). To implement this study, all chickens will be vaccinated at 18 weeks of age. At 25 weeks of age, the chickens will be challenged with SE. At 26 weeks of age, the chickens will be examined for colonization of SE in the cecum. The response variable of the study is binary, whether SE can be detected or not. The variables that might influence the response variable are vaccine administration methods, SC and IM. However, we have noticed that there are various other factors thought to influence the detection of SE. For example, the types of chicken breeds used in this study were not mentioned, different types of chicken breeds may react differently towards the client's vaccine and SE. We believe that clarification is needed from our client.

Data

The sample population for this study is 157 commercial chickens in North America. Each of them was assigned to the following groups:

1. Vaccine group A, vaccine administered SC.
2. Vaccine group B, vaccine administered IM.

3. Control group C, placebo (some administered SC and some administered IM).

According to the sample table provided by the client, this is recorded in the second column named “Group” corresponding to each chicken’s ID number in the first column. The binary response variable is recorded in the third column named “Cecum” as the chickens were examined for colonization of SE in the cecum, positive (1) for colonization if the challenge strain of SE was re-isolated and negative (0) for colonization if not re-isolated. Our client did not provide a data collection protocol other than the sample table provided. We suggest that the data of this study be recorded electronically and ready for performing analysis using R or SAS. We have learned that not all 157 chickens used in the study are alive at 26 weeks of age during the meeting section with our client. We recognize that potential study error might have occurred due to missing data as it causes a difference between the target population attributes and the study population attributes.

Proposed Analysis

Relative risk (RR) is our proposed method for this study. It is often used when the study involves comparing probabilities (Bilder & Loughin, 2015, p. 37). Our client is interested to show that the proportion positive for post-challenge SE colonization is lower for each of the vaccinated groups (A, B) compared to the control group (C). Estimated RR can be calculated through a 2*2 contingency table (Bilder & Loughin, 2015, p. 38). In this study, we will be required to build two 2*2 contingency tables, so that we can compare the RR between vaccinated group A vs. control group C and vaccinated group B vs. control group C. The binary responsible variable needs to be counted and reorganized to the corresponding vaccinated group. Bilder and Loughin (2015) suggest using R to transform the sample data into an array and to perform the necessary calculations for estimated RR (Bilder & Loughin, 2015, p. 39). By industry guidelines,

a 95% confidence interval for estimated RR can also be generated by using R. According to Bilder and Loughin (2015), causal effects are assumed when interpreting estimated RR (Bilder & Loughin, 2015, p. 39).

Conclusion

From our proposed analysis, we are expecting two RR values with their 95% confidence intervals. If our client's vaccine prevents SE regardless of administration methods, then we should expect both RR values to be very close to 1 with their 95% confidence intervals in a similar range. We noticed that the potential study error mentioned previously may influence the estimated RR values. For example, we can assume that our client's vaccine prevents SE regardless of administration methods. However, one of the administration methods leads to a higher death rate for the chicken and hence, more discarded data in the dataset. The RR values calculated from such data set can be misleading.

References

Bilder, C. R., & Loughin, T. M. (2015). *Analysis of categorical data with R*. Boca Raton: CRC Press, Taylor & Francis Group.