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Research Feasibility Group: Perception of Successful and Failed Clinical Trials

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Background: Conducting a successful clinical research trial is a complex process. The evaluation of a new protocol is an important first step in determining whether a prospective clinical research trial will recruit the expected number of patients in the allocated period of time. Our research feasibility group comprised of a principle and co-investigator(s), a clinical research manager, an investigational drug pharmacist, and a clinical research coordinator is responsible for assessing all new clinical trials. We developed a protocol assessment feasibility tool to aide in predicting successful industry-sponsored clinical trials.

Methods: A 67-item questionnaire was developed focusing on 5 specific domains: the trials' key sponsors, the institution conducting the research, the Institutional Review Board, the patient population, and the trials' protocols and procedures. Fifteen industry-sponsored clinical trials that had been successful (i.e., met study enrollment goals within the designated time) and 15 industry-sponsored clinical trials that were unsuccessful (i.e., did not meet study enrollment goals within the designated time) were identified and randomly assigned for review by our research feasibility group. Each member of the feasibility group was asked to complete the 67-item questionnaire for each of their assigned clinical trials.

Results: The content validity of each of the 67 items of the questionnaire was computed and was used to select or eliminate items from the questionnaire. All items without a statistically significant nor high content validity (i.e. p-value >0.05 or r < 0.44) were eliminated. Twenty questions with statistically significant high content validity (i.e. p-value <0.01 and r >= 0.50) were retained. The internal consistency reliability for the 20 retained items (raw variables) was 0.95. The Wilcoxon Rank-Sum test revealed a significant difference in the total scores of the final 20-item questionnaire between successful and failed clinical trial groups (p-value = 0.0294, mean of successful group = 73.79 and median = 74.58; mean of unsuccessful group = 70.43 and median = 71.50). A total score of 70 was used as a cutoff to classify the successful and unsuccessful clinical trials (i.e., a trial with a total score greater than 70 was classified as successful). This cutoff correctly classified 70% of the trials, with a sensitivity of 0.93 and a specificity of 0.47.

Conclusions: Initial piloting of this assessment tool demonstrated ability of the tool to discriminate potentially successful and unsuccessful clinical trials. However, further testing is necessary to define sensitivity limits and tool validity.