

FDA Advisory Committee Process Project: Improving Committee Selection for Experts and Members.

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Introduction

Through a number of referenda, the Advisory Committee selection process within the FDA, has been specifically addressed in order to accelerate assignment and initiate the evaluative processes for the respective committees. In many instances, the conflict of interest statement or insinuation of bias was prohibitive to a committee assignment, thus causing unnecessary delays or excluding a sound candidate from participation.

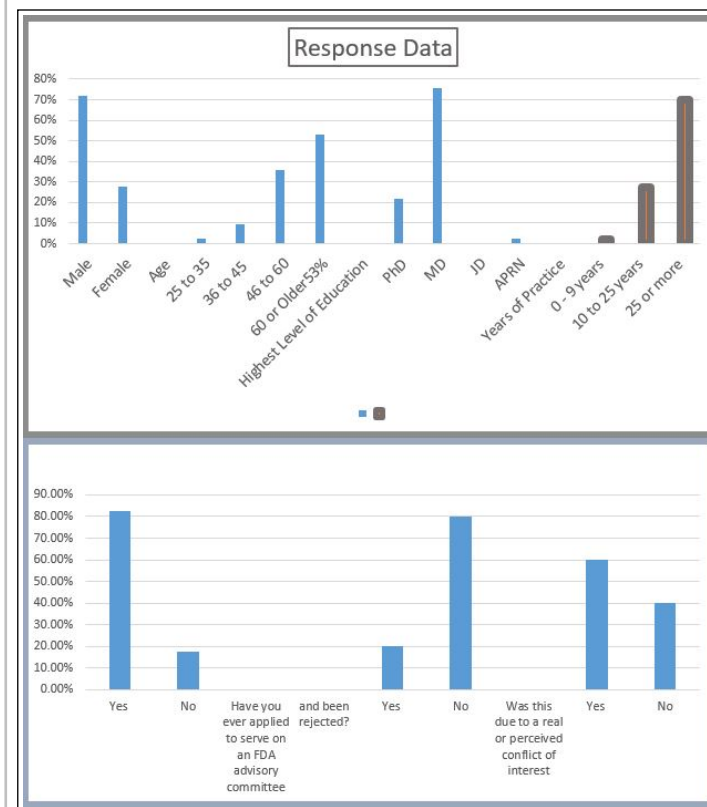
The objective of this study was to extract both internal and external observations on making this selection process more fastidiously, subsequently adding efficiencies to known delays and evaluations at the Advisory Committee Level

Methods

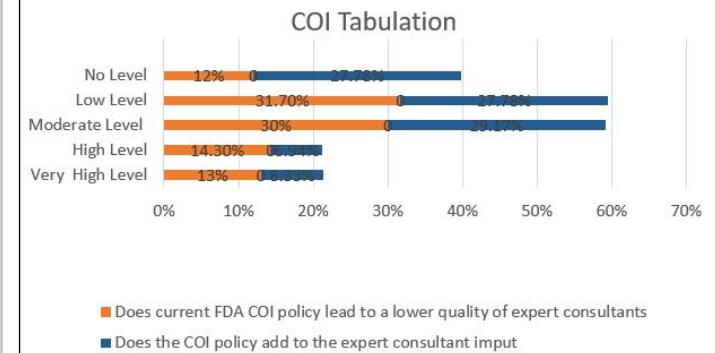
A number of internal and external inquiries through questionnaire and dialog were accrued from industry, academia and private sector individuals who had direct contact or involvement with Advisory Committee processes. These opinions (> 25 individuals) were then collated for patterned observations in order to construct a list of redeemable recommendations for submission to the directorship of the FDA. A bibliographical search of media and literature assisted in eliminating duplicity and focus of our recommendations.

Objectives

The commonality of observed delays by both internal and external participants involved the cumbersome process of selection and exclusion criteria. Addressing the current policy on conflict of interest will make a significant difference in process efficiency, but also allow for more expert placement.



Results



Conclusions/Recommendations

- Expert selection should be based on multiple criteria, and not solely excluded on conflict of interest. Disclosure and bias statements are helpful in expert selection and may allow for more experts, faster selection and more alacrity added to the already bottlenecked process.
- Currently this study is ongoing.
- The majority of respondents (73%) (Question 10, Does COI exclude qualified candidates from Serving on the Advisory Committees) acknowledge this fact of exclusion.
- The FDA leadership and this study group is diligently assessing methods to re-engage and maintain the best possible experts to assist in Advisory Committee duties.

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