DISCUSSION

While professional subjects who are “destined to fail” have a marginal impact on statistical power, those who are “destined to succeed” appear to be the greatest threat to medications development. Figure 1 demonstrates that a fairly small percentage of these subjects can have an insurmountable impact on the evaluation of medication efficacy within a study population. This example illustrates that a heroic increase in sample size can restore statistical power (Figure 1, panel B), but even large samples are challenged by a decrease in apparent effect size (Figure 1, panel C). If we accept the possibility that increasing numbers of professional subjects have been feigning psychiatric illnesses to gain enrollment in efficacy trials, the implications are clear. We must either improve our ability to identify and exclude such subjects from trials or design trials that mitigate their impact.

REFERENCES


DISCLOSURE

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