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| **Date of Review** |  |
| **Reviewer Name** |  |
|  |  |
| **JeffTrial#** |  |
| **Principal Investigator** |  |
| **Protocol Title** |  |

# Protocol Critique

Are the primary and secondary objectives scientifically sound? [ ]  Yes [ ] No

Please comment.

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Is the study design appropriate to meet the objectives? [ ]  Yes [ ] No

If not, how might it be improved?

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Are the endpoints adequately described and appropriate to the study objectives? [ ]  Yes [ ] No

Please comment.

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Are the planned analyses appropriate? [ ]  Yes [ ] No

Please comment.

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Is the sample size sufficiently justified? [ ]  Yes [ ] No

Please comment.

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Additional comments or questions concerning the statistical design.

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# Outcome

Is the biostatistical design appropriate? [ ]  Yes [ ]  No

Concerns to be address before the study should be approved.

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Other comments.

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**Preliminary recommendation:** [ ]  Approve

 [ ]  Contingent Approval

 [ ]  Defer

 [ ]  Disapprove