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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