DSMB II

* 1. Coder

- ◯ Matthew
- ◯ Joe
- ◯ Jen
- ◯ Rachel
- ◯ Jackie
- ◯ Jenna

* 2. Article

* 3. Journal

- ☐ Anals of Internal Med
- ☐ BMJ
- ☐ JAMA
- ☐ JAMA Internal Med
- ☐ Lancet
- ☐ NEMJ

* 4. Type of disease / condition that is being treated by the intervention

- ◯ Cancer
- ◯ Neurological (e.g., movement disorders, cognitive disorders and impairment, pain)
- ◯ Cardiovascular
- ◯ Infectious diseases (e.g., viral and bacterial infections)
- ◯ Obesity
- ◯ Pregnancy outcomes
- ◯ Smoking cessation
- ◯ Gastro/intestinal disorders other than cancer (e.g., GERD, IBS)
- ◯ Diabetes
- ◯ Orthopedic
- ◯ Psychiatric
- ◯ Other (please specify)

* 5. Prevention of disease or treatment of disease?

- ◯ Prevention
- ◯ Treatment

* 6. Sponsor (please check all that apply)

Please be sure to look in foot notes on the cover page, the acknowledgements section, any sections labeled conflict of interest, and check to see if they describe who supplied a drug or device.

- ☐ Industry
- ☐ Government Agency
- ☐ Academic Institution / Departmental funds
- ☐ Professional foundation
- ☐ Not reported

* 7. Type of intervention (please check other if multiple types and write them all in the box provided)

- ◯ Non-invasive pharmacologic (including supplements, topical and inhaled substances)
- ◯ Invasive, pharmacologic (e.g., I.V., intrathecal injections)
- ◯ Surgical (other than device implementation; include surgeries that insert hardware (such as rods in the spine) in this category)
- ◯ Invasive device (i.e., requires an operation to implant, e.g. spinal cord stimulator)
- ◯ Non-invasive device (i.e., TENs device)
- ◯ Radiologic intervention
- ◯ Biologic intervention
- ◯ Behavioral / psychological
- ◯ Physical Therapy
- ◯ Dietary
- ◯ Genetic therapy
- ◯ Other (please specify)

* 8. How many subjects were randomized?

* 9. Was the trial blinded

- ◯ Yes, double blind (i.e., all research staff that made contact with the participants and the participants were blinded)
- ◯ Yes, modified double blind (i.e., participants and assessors are blinded, but the person performing an invasive procedure or administering a non-pharm intervention is not blinded)
- ◯ Single-blind (i.e., only the participants or the investigators are blinded)
- ◯ No (i.e., participants and researchers are not blinded to the treatment assignment).
- ◯ Other (please explain any blinding that doesn't fit in the other categories (e.g. the person administering the treatment and the patients are not blind, but the assessor is)

* 10. Did the trial include any of the following vulnerable subjects?

- ◯ Children / pediatric patients
- ◯ Pregnant women
- ◯ Cognitively impaired
- ◯ None

Please note anything important here

* 11. Were participants recruited from more than one site?

- ◯ Yes, the authors directly state that the trial was multi-site
- ◯ No, the authors directly state that the trial was single-site
- ◯ Not directly stated, but the authors mention IRB approval at multiple institutions, suggesting the trial was multi-site
- ◯ Not directly stated, but the authors mention IRB approval at only one site, suggesting the trial was a single site trial.
- ◯ Unclear

please note any clues about the number of sites here that don't fit the answers above

12. Where did they mention the DSMB members (check all that apply)

- ◯ methods
- ◯ results
- ◯ discussion
- ◯ acknowledgements
- ◯ Other (please specify)

13. Was the trial stopped earlier than planned?

If the number randomized is within 95% of or greater than the number indicated in the sample size calculation check no, otherwise check Methods, results, and discussion for mention of early stopping.

- ◯ Yes
- ◯ No

If yes, please describe below

14. What was the length of the randomized phase? (in weeks) (longest time of follow-up)

If unclear, please make a note

1 year= 52 weeks; 6 months = 26 weeks; 3 months = 13 weeks
If anything less, multiply months by 4
For months more than 1 year, use the above to add up the number of weeks

15. Were the data presented to the DSMB in the following ways?

- ◯ blinded
- ◯ semi-blinded
- ◯ unblinded
- ◯ N/A, no DSMB mentioned
- ◯ N/A, mentions a DSMB but does not say how the data were presented
- ◯ Other, please specify

16. Did the authors indicate the frequency with which the DSMB members had access to the data?

- ◯ Yes
- ◯ No
- ◯ N/A, no DSMB

notes

DSMB II

* 17. Is involvement of a Data and Safety Monitoring Board or Independent medical monitor reported? (Key words / phrases to “control F” for: DSMB, DSMC, IDMC, DMC, IMC, monitor, independent, board, committee)

- ◯ Yes, use of a DSMB was reported in the article (note this includes any monitoring committee)
- ◯ Yes, use of an independent medical monitor was reported in the article (note, this is meant to indicate only one person)
- ◯ Investigators stated that a DSMB or independent medical monitor was not used
- ◯ Not reported

Other (please specify)

* 18. If a DSMB / independent monitor was not used, did the authors state why not?

- ◯ Yes
- ◯ No
- ◯ N/A, a DSMB / independent monitor was used

If a reason was given, please record it in the box

* 19. If the article reported a DSMB or independent monitor, were the DSMB’s / independent monitor’s responsibilities described? Note: If the authors simply state that "oversight was provided" by the DSMB, the answer to this question is no.

- ◯ Yes (choose this question if they mention a conclusion made by the DSMB upon which you can infer at least one of the responsibilities)
- ◯ No
- ◯ N/A, a DSMB / independent monitor was not reported

* 20. If the article reported a DSMB or independent monitor, were thenames OR titles (e.g., statistician, clinician, epidemiologist) of the members listed.

- ◯ Yes
- ◯ No
- ◯ N/A, no DSMB

* 21. If the article described DSMB / independent monitor responsibilities, which of the following were mentioned (check all that apply)?

- [ ] Monitor trial performance (e.g., recruitment, retention, data quality, protocol adherence)
- [ ] Monitor safety data (i.e., adverse events, AEs)
- [ ] Monitor efficacy data for early evidence of futility or efficacy (i.e., interpret an unblinded analysis to determine if there is a very low chance that the trial will demonstrate a significant treatment effect even when full recruitment has been reached OR interpret an unblinded analysis to determine if there is a very low chance that the trial will **NO LONGER** demonstrate a significant treatment effect once the remainder of the subjects are recruited, respectively). Note: the goal of one of these analyses is to decide whether or not to STOP THE TRIAL EARLY
- [ ] Authors state something like "Monitor data", but don't supply anymore details than that
- [ ] Advise on sample size re-estimation based on blinded evaluation outcome variability
- [ ] Advise on trial adaptations (**other than** blinded sample size re-estimation or evidence of futility or early efficacy) (applies to things labeled adaptive designs and interim analyses, etc.) Examples include decisions on whether or not to change the randomization ratio or to drop one arm and continue with the others. NOTE: the goal of this type of analysis should NOT be to decide whether or not to stop the trial early.--- **if check this option, please describe in detail in the other box below** .
- [ ] Evaluate final efficacy analyses
- [ ] Provide comments on one or more manuscripts being submitted for publication
- [ ] Provide input on and/or approve the protocol
- [ ] They did not directly list the responsibilities of the DSMB, but they did state a conclusion of the DSMB's (For example, they state that the DSMB did not find any substantial difference in adverse events between treatment and placebo groups). -- **if you check this answer, please describe in the other box below**
- [ ] The responsibilities were not described
- [ ] N/A, no DSMB was reported.
- [ ] Other (please specify)

* 22. Where in the article was the DSMB / independent monitor mentioned (check all that apply)?

Please include any mention of interpretations that were obviously made by the DSMB even if DSMB is not mentioned in the section (e.g., if they say in the methods section that the DSMB was responsible for a futility analysis and then in the results section they say that the trial was stopped for futility, but don't actually say the phrase DSMB in the results section, please check both methods and results section

- [ ] Footnote
- [ ] Acknowledgements section
- [ ] Methods section
- [ ] Results section
- [ ] Discussion section
- [ ] N/A, no DSMB or independent monitor mentioned

Other (please specify)

* 23. Were any changes reported that were made to the trial design, execution, analysis, or data interpretation based on the DSMB's / independent monitor's recommendations? ***Please Note: if you checked that the responsibilities of the DSMB were listed, you **CANNOT rely on control F for this question** because the outcome of the DSMB's decision may be stated far away from the actual phrase DSMB. You must read the entire results section. For example, it may say in the methods section that the DSMB was responsible for interpreting an interim futility analysis and then in the results section say that the trial was stopped for futility, but not actually re-state that the DSMB made this decision.****

- ( ) Yes, please explain below.
- ( ) No
- ( ) N/A no DSMB or independent monitor mentioned

Please explain changes made in the box below