19 August 2022

03:06 GMT

Dear Elise -

Thank you for sharing your updated review and ranking. While we disagree on some of the rankings, this exchange has been helpful to understand how external groups may analyze and interpret our policies.

With that in mind, we identified a few places where clarification will be helpful based on the information you have shared. This is intended to ensure you have a fuller picture of our policies, processes and expectations for our awardees as they are intended.

Specifically:

- *Regarding reporting*, we require reporting to the Association, and that includes any publications or presentations and updates to their registry listing. The regular check-ins do include an ask about the status of sharing information about their study -- including trial design. In practice, this includes updates about study generally and about their registry listing. We independently also review this; however, as you note, this is not explicitly stated as a requirement to update and we have added language in our reporting language to be more clear of this expectation. In our lens with this clarified language, this would be a YES FULL.
- For *trial ID in publications*, this is a requirement of journals in our space including the three journals owned by the Association. However, we understand your interpretation and are adding a sentence that requires any publication to include reference to the trial ID. With this additional language, this would be YES FULL. You note, *some trials are required to be listed in a registry*. It is unclear what you mean by "some." This is something we've actively included as part of this tracking and monitoring for awards made over the last three years and are currently required for awardees as part of their milestones. In our lens, this should be YES FULL.
- For the *PI past record*, this is in practice part of the discussion; we review the investigator and the entire study team, their past trial experience, completion and reporting on their trials as part of the review criteria and the panel discussion. We appreciate your suggestion of asking the lead investigator to provide a summary of past trials and their reporting of their trials. We are implementing this for our application process. With this addition, this would be YES FULL.

In addition, we are seeking additional clarification: "non-binding" is listed for "monitoring trial" and "not at all" for the "monitoring results." It is unclear to us what you mean by this. Withholding payments for studies that do not meet their milestones is binding. What sort of steps would you want to see that would give you a sense that this is binding?

We appreciate your review, the opportunity to provide additional context and welcome additional feedback in advance of reading the manuscript. Thank you.

Sincerely

[redacted]