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Letter to the Editor - Response

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To the Editor

We are grateful to Arai and colleagues for their comments.

We agree that payment to phase 0 oncology trial participants must be carefully considered. However, to the extent that healthy volunteers are paid to participate in research that does not offer the prospect of direct benefit, the same modest incentives should be considered for cancer patients who are enrolled in nonbeneficial studies. Research in the developing world raises additional concerns; yet, insofar as people in developing countries are offered compensation for participating in research, phase 0 oncology trial participants in these regions should not be overlooked. Paying patients is a potential strategy for combating the therapeutic misconception in nonbeneficial research, and one of the key arguments against paying subjects, their receipt of medical treatment, is not applicable in the context of phase 0 trials [1].

Aria and colleagues rightly point out that the population likely recruited to participate in phase 0 trials, terminally ill cancer patients, will not benefit directly from the research. Extending post-trial access to drugs that prove successful in phase III trials to patients who were enrolled in earlier-phase research is certainly worth evaluating; nevertheless, it may not be the best strategy to maximize benefits to participants. Many drugs fail before reaching even late-phase trials, and the late-stage cancer patients who participate in phase 0 trials may not survive to see successful drugs reach efficacy studies. One important policy to implement is to ensure that participants are not excluded from trials that may benefit them merely because of their previous participation in phase 0 studies [2,3].

References

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