Author's response to reviews

Title: Industry-Sponsored Clinical Research in Less-Developed Regions: An Empirical Analysis of Registered Clinical Trials from 2006-2013

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Author's response to reviews: see over
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Dear Editors of Health Research Policy & Systems,

Please find attached a manuscript titled 'Industry-Sponsored Clinical Research in Less-Developed Regions: An Empirical Analysis of Registered Clinical Trials from 2006-2013'. We are submitting the paper for consideration in the Research section of your journal, after a recommendation from the editors of BMC Public Health.

Clinical research is occurring in less-developed regions in greater quantities and with it arise a number of controversies related to the ethical conduct of research in these populations and the applicability of the results to larger populations. The magnitude of this transition remains to be currently quantified.

This original work documents this shifting landscape of clinical research performed by industry across geographic and economic regions. We have examined greater than 22,000 trials over a recent 8-year period, over 6,000 of which recruited participants in less-developed countries. Our aim was to quantify and characterize participant recruitment from less-developed nations and to measure differences in trial design and conduct between less- and more-developed regions of the world, using the largest trial registry as our data source. We found that greater than a quarter of trials enroll participants from less-developed nations and this quantity has not appreciably changed over the past 8 years; however, research in less-developed nations is concentrated within certain regions. Trial characteristics are significantly different between those conducted in more-compared to less-developed nations.

We look forward to hearing your thoughts on the suitability of this work for publication in your journal. The authors have no conflicts of interest to declare.

Sincerely,

Srinivas Murthy