Dear Dr. D’Souza,

Thank you for the very quick initial review. Please allow us to respond to the following points you mentioned in your email:

- It appears that a systematic review and analysis has been carried out on this study. Please can you adhere to PRISMA guidelines as follows: http://www.prisma-statement.org/. Please indicate what type of statistical analysis was carried out- was this a meta analysis?

- Our analysis was a sub-analysis of a systematic review (without meta analysis) that some of us published earlier in Plos One (“Room for improvement in conducting and reporting non-inferiority randomized controlled trials on drugs: a systematic review”, http://www.plosone.org/article/info:doi/10.1371/journal.pone.0013550). Hence, we are doubting whether PRISMA guidelines will be suitable for this kind of analysis. Please find attached the PRISMA guidelines we made for our previous review. The statistical analysis we did in our current article is univariate/descriptive analysis.

- Please clarify the aims of the study and indicate what the claims of benefit are

   - We revised the background section (please see highlighted part in the main text) to read as follows:

     "We aimed to determine 1.) whether these trials reported benefit claims beyond clinical efficacy (such as improved safety, optimized method of administration, improved compliance, cost-effectiveness, and others); and 2.) how these additional claims were supported or proven in the trials."
• Indicate in the title what the additional claims of the benefit is

-Since the aim of the study was to determine whether Phase IV NI trials reported (any) additional benefit claims beyond clinical efficacy and how these claims were supported or proven in the trials, and thus, we did not aim to see whether certain additional benefit were claimed, we cannot write any specific benefit claim in the title.

• It would be helpful if you can indicate all this points in the manuscript which needs to be formatted for a research article. Guidelines are indicated in the following link:
http://www.biomedcentral.com/bmcmed/authors/instructions/researcharticle

-We have revised the manuscript to comply to the guidelines. Please see the highlighted sections.

Thank you very much for considering our manuscript. We hope we have sufficiently responded to your concerns.

Kind regards,
Rosemarie Bernabe and
Grace Wangge