Reviewer's report

Title: Infliximab for pediatric patients with ulcerative colitis: a phase 3, open-label, uncontrolled, multicenter trial in Japan

Version: 0 Date: 03 Jul 2019

Reviewer: Alan Ngo

Reviewer's report:

Dear Authors,

Thank you very much for the opportunity to read your paper. It is very well written with an excellent discussion and good use of figures. I was surprised that this was the first trial performed in patients from an Asian background as it has become the first line biological agent in hospitals that I have worked at for many years. Is there any evidence that Asian patients respond differently to biological treatments for other conditions compared with Western patients that further justifies this trial?

In the Methods, as a non-paediatric gastroenterologist, I would like you to describe why you chose the CAI, PUCAI and MAYO scores as your outcome measures. What is the benefit of using all 3 classification systems as outcome measures as compared with using just 1 classification system? Given that there are non clinical measures in these classification systems, is there an opportunity to introduce bias?

Overall this paper is well written and the limitations - small sample size- have been addressed.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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