Author’s response to reviews

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

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Author’s response to reviews:

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Amelia De Salis
Assistant editor
BMC Pediatrics

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Dear Ms De Salis,

On behalf of my co-authors, I would like to resubmit our manuscript entitled “Infliximab for pediatric
patients with ulcerative colitis: a phase 3, open-label, uncontrolled, multicenter trial in Japan” for consideration for publication in BMC Pediatrics as a Research Article.

We have attached our responses to your comments below. Please note that the page and line numbers in our responses refer to those in the resubmitted manuscript.

We have also revised the manuscript according to your comments, and hope that it is now acceptable for publication in BMC Pediatrics.

We look forward to hearing from you after the re-evaluation of our manuscript.

Thank you again.

Yours sincerely,

Hitoshi Tajiri

Response

Comment 1.

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided in the Declarations.

Response: We have added a list of abbreviations to the Declarations section (Declarations section, line 352-357, page 17).

In addition, we have ensured that all abbreviations have been defined at first use. For “anti-tumor necrosis factor-α”, we have revised relevant sentences in the Background section such that the full term, rather than the abbreviation (anti-TNF-α), is used because it only appears twice in the text. The sentences have been revised as follows (Background section, line 72-75, page 4):

“Several randomized studies have reported the efficacy and safety of anti-tumor necrosis factor-α agents for adult and pediatric patients with UC [9–12]. Infliximab (IFX), an anti-tumor necrosis factor-α monoclonal antibody, is approved for induction and maintenance treatment of pediatric UC in a number countries outside Japan and is the first biological treatment of choice [6].”

Comment 2.

Patients:

Please add a “Conclusions” section after the “Discussion” section. This should state clearly the main conclusions of the research article and give a clear explanation of their importance and relevance.
Response: Given that we had written a conclusions paragraph at the end of the “Discussion” section in the original manuscript, we have moved this paragraph to the “Conclusions” section and added the following sentence to indicate the importance and relevance of our study (Conclusions section, line 342-350, page 17):

“These results support the use of IFX in the treatment of pediatric patients with UC with inadequate response to existing treatment.”

Comment 3.

In the section 'Funding', please also describe the role of the funding body/bodies in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Response: Thank you for this instruction. We have added the role of the funding body to the Funding section as follows (Funding section, line 401-403, page 19):

“Mitsubishi Tanabe Pharma Corporation was responsible for the collection and analysis of data, and was involved in establishing the study design and the interpretation of data.”