Author's response to reviews

Title: Evaluation of Efalizumab using Safe Psoriasis Control

Authors:

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Author's response to reviews: see over
Dear Sandra,

Thank you for considering our manuscript for publication in your journal – we are glad that one of the reviewers considers this article to be of importance to your readers. We have considered all the comments and addressed all of them in full.

The main concern about the discrepancy between the purpose of the study and the conclusions has been resolved by clarifying the wording used to express the aim of study. Our detailed response to this comment, as well as the other comments, is provided in the table below.

We hope that you will consider the revised manuscript favourably (attached) and feel that we have done our best to address the reviewer’s comments.

Yours sincerely,

Eric Henninger

**Reviewer: Steven Feldman**

**Comment 1:**
The Purpose of the study and the Conclusion are incongruous. The Purpose reads as an assessment of an instrument. The Conclusion reads as an assessment of a drug. There’s nothing (or at most very little) new here about the drug. There’s nothing new about the validity of the SPC measure, either, as far as I can tell.

**Response 1:**
To remove this incongruity, we have changed/clarified the purpose of the study in the Abstract to read: ‘The objective of this analysis was to assess the benefit:risk of efalizumab, a novel biologic agent indicated for the treatment of moderate-to-severe plaque psoriasis, by applying the SPC to data from three randomized, placebo-controlled clinical studies of efalizumab.’ A similar sentence has also been added at the end of the Introduction to state more clearly the purpose of our analysis.

**Comment 2:**
Consider changing ‘has been shown to’ and its various other forms to ‘is’.

**Response 2:**
We couldn’t find an instance of the wording ‘has been shown to’ in the manuscript. However, we have substituted instances of ‘has been’, ‘was shown’, ‘have previously shown’ and ‘was to’ for more direct English:

− Abstract (first sentence): ‘has been proposed as’ swapped for ‘is’.
− Abstract (last sentence): ‘was shown to have’ swapped for ‘has’.
Background (2nd paragraph): ‘has been developed in response to the need’ swapped for ‘is designed’.

Discussion (2nd paragraph, 3rd sentence): ‘Many authors have previous shown the need to consider’ swapped for ‘Studies indicate that there is a need to consider’

Discussion (3rd paragraph, 1st sentence): ‘The purpose of this paper was to apply’ swapped for ‘We applied’.

Comment 3:
There ought to be more than a poster reference for the Koo-Menter instrument.

Response 3:
This instrument has now been referenced to Feldman et al: J Am Acad Dermatol 2005, 53(1):101-107. In accordance with the terminology used in this article, the wording 'Koo Menter index' has been updated to read 'Koo-Menter Psoriasis Instrument'.

Reviewer: Jennifer Cather

Comment 1:
Clarify when your endpoint was – I think it was week 12 for all studies mentioned. Consider adding “at week 12” to tables 2 and 3 for clarity. If a patient had an SAE or AE which necessitated discontinuation or a PASI >8 after endpoint, how did you treat the data?

Response 1:
Yes, the SPC was used to analyse week 12 data. We have added this information to the Abstract, Methods and Results sections, as well as to Tables 2 and 3.

With respect to patients who discontinued or had a PASI >8 after the study endpoint – we didn’t consider patient data after the week 12 endpoint. However, if a patient experienced an SAE or withdrew from a study, the patient was considered as a non-responder after the start of the event, regardless of when the event ceased.

Comment 2:
Should you include what the DLQI actually is for people who do not use it daily?

Response 2:
We have now defined DLQI and briefly described what it is used for in the Methods section.