Author’s response to reviews

Title: Rational, Objectives and Design of PURE, a Prospective Registry of Patients with Moderate to Severe Chronic Plaque Psoriasis in Canada and Latin America

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The authors thank the Editor and the Reviewer for their thoughtful comments. Our point-by-point response to their comments is given below.

1. Ethical and Funding Approval Documentation.

Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. These documents should be sent as email attachments to the following email address, bmcdermatol@biomedcentral.com. Please DO NOT upload these documents as additional files in the submission system. If your documents are not in English, please could you provide translated versions of the relevant parts. These should be endorsed and signed by a contactable person at the institution. Please also include the original
documents. Can you please confirm in your cover letter that you have forwarded the requested documentation to bmcdermatol@biomedcentral.com.

Response: There are 72 sites across Canada and Latin America, which had ethical submission and approval and have initiated this study. The approvals from Latin America were submitted and received in Spanish and Portuguese and their translation to English may be costly and time consuming. Please suggest an alternative method of providing these documents, such as, providing documents in the original language, with a signed statement from Novartis confirming that all sites received Ethics approval. We are mailing all the original ethics committee approvals to the suggested email address: bmcdermatol@biomedcentral.com

2. Ethics Approval for All Sites.

Thank you for listing all of the Ethics committees/Institutional review boards that have approved your study. However, please could you clarify whether these ethical approvals cover all of the study sites involved in this study.

Response: Please find the list of participating sites with their current status with and corresponding EC type and name. This list covers all study sites that were initiated.

3. Funding

A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board. If a study has received funding/assistance from a commercial organization, this should be clearly stated in the 'competing interests' section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board. Can you please confirm whether your study protocol has undergone peer-review by the funding body.

Response: This study is 100% funded by Novartis Canada and no external funding body was involved.

4. Study status

The protocol must be for a study that is ongoing. An ‘ongoing’ study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.
Response: This study is in recruitment phase until Dec-2019 (expected LPFV) and will be ongoing until Dec-2024 (expected LPLV)

5. Related Articles

Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles.

Response: The manuscript has not been submitted or published so far. Several abstracts/posters were published at various congresses. A list of publications as of today containing the following information: publication type; publication title; Authors; Congress name; Publication Date has been sent to bmcdermatol@biomedcentral.com.

The addition of a new author has been requested and the author change form has been sent to bmcdermatol@biomedcentral.com.