Author’s response to reviews

Title: Effectiveness, safety and health-related quality of life of multiple sclerosis patients treated with fingolimod: results from a 12-month, real-world, observational PERFORMS study in the Middle East

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Author’s response to reviews:

To
Editor-in-Chief
BMC Neurology

Subject: Manuscript addressing reviewers’ comments (manuscript ID: NURL-D-16-00638)

Dear Editor,

We thank the reviewer for a thorough assessment of the responses provided and the changes implemented in our manuscript entitled “Effectiveness, safety and health-related quality of life of multiple sclerosis patients treated with fingolimod: results from a 12-month, real-world
observational PERFORMS study in the Middle East”. The minor changes we have made are highlighted in track mode in the revised version.

We hope that the revisions/explanations provided make our manuscript more satisfactory for publication in BMC Neurology journal and would like to thank you in advance for considering the revised version.

Looking forward to hearing from you.

Thank you again for your consideration.

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Comments to the Author

Pasquale Annunziata (Reviewer 1): This new version of the manuscript has partly met the reviewers' suggestions. The main concern remains the lack of any statistical attempts just for Kaplan-Meier curves and EDSS comparisons. If the authors present both curves in Fig. 4, it is mandatory to show log rank values, otherwise they should present separate curves in different panels of the fig. 4. However, due to the characteristics of the study, the authors should add to discussion a paragraph displaying the limitations of the study including the reasons of the lack of neuroimaging findings and difficulties to compare the findings of both cohorts. This should be highlighted in the abstract too.

Response: Thank you for the comments. In the revised version, we have separated Figure 4 into two different panels for ‘Fingolimod cohort’ and ‘Other DMTs cohort’. Per suggestion, we have included the following sentences regarding neuroimaging findings in different sections of the manuscript:

• Abstract section (page 2, para 2, line no. 43–45):
  Due to the observational nature of the study, no neuroimaging assessments were mandated and central reading was not performed.

• Methods section (page 6, para 2, line no. 141–142):
  Due to the observational nature of the study, no neuroimaging assessments were mandated and central reading was not performed.

• Discussion section (page 18, para 2, line no. 430–433):
  As PERFORMS was a real-world, observational study, no neuroimaging assessments were mandated and MRI read outs were not evaluated via a central reading facility. Therefore, neuroimaging findings were not considered as an outcome to be assessed.

(Note: The authors' response letter has been included as a supplementary file)