National Institute for Health and Care Excellence
Centre for Health Technology Evaluation

Pro-forma Response

ERG report

Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy

You are asked to check the ERG report from **School of Health and Related Research (ScHARR), The University of Sheffield** to ensure there are no factual inaccuracies contained within it.

If you do identify any factual inaccuracies you must inform NICE by **5pm** on **10th November 2014** using the below proforma comments table. All factual errors will be highlighted in a report and presented to the Appraisal Committee and will subsequently be published on the NICE website with the Evaluation report.

The proforma document should act as a method of detailing any inaccuracies found and how and why they should be corrected.

Issue 1 Patient Population in Gemini 2 and Gemini 3

Description of problem	Description of proposed amendment	Justification for amendment	ERG response
The patient population included in Gemini 2 and Gemini 3 is incorrectly described throughout the report	Enrolled patients had failed at least one conventional therapy, including corticosteroids, immunomodulators **and** or TNF-alpha antagonists (primary and secondary non-responders).	This proposed amendment accurately reflects the included patient population for both studies.	The ERG agrees with the proposed amendment. This has been amended on Page 1, 14, 15, 17, 28, 30, 40, 41 and 117 of the ERG report.

Issue 2

Description of problem	Description of proposed amendment	Justification for amendment
Give full details of inaccuracy found including page number in ERG report	Give details of any corrections that should be made	Justify why the error needs correcting and the impact it will have

Issue 3

Description of problem	Description of proposed amendment	Justification for amendment
Give full details of inaccuracy found including page number in ERG report	Give details of any corrections that should be made	Justify why the error needs correcting and the impact it will have

(please cut and paste further tables as necessary)