

Subrata Gosh, MD, Full Professor

April 08, 2020

Andrzej S Tarnawski, MD, PhD, Professor

World Journal of Gastroenterology

Dear Professor Gosh,

Dear Professor Tarnawski,

It is my great pleasure to resubmit the revised manuscript "Golimumab in real-world practice in patients with ulcerative colitis: 12-month results from a prospective, multicenter, non-interventional study in Germany" for additional evaluation to the *World Journal of Gastroenterology*. The manuscript has been revised based on the suggestions of the reviewer (peer-review report) and the science editor. Our responses are given in a point-by-point manner below. We attached one additional raw revised draft version of the manuscript with track changes in *Supplementary Material* for your convenience. This file should be deleted after your review.

In addition, we uploaded the file "54575-Approved Grant Application Form(s) or Funding Agency Copy of any Approval Document(s)" as requested.

We hope the revised version is now suitable for publication and look forward to hearing from you in due course.

Thank you very much for your time and attention!

Sincerely,

Prof. Dr. Niels Teich

Internistische Gemeinschaftspraxis für Verdauungs- und Stoffwechselkrankheiten
Leipzig and Schkeuditz

Nordstr. 21

04105 Leipzig

Germany

Email: teach@igvs.de

Response to reviewer:

Thank you for the positive feedback and helpful comments.

Comment #1:

However, I consider it appropriate to slightly change the name to “Golimumab in real-world practice in patients with ulcerative colitis: 12-month results from a prospective, multicenter, non-interventional GO-CUTE study in Germany”.

Response #1:

We changed the title of the manuscript accordingly but we renounce of the study title GO-CUTE. Our previous title was kept short due to the guidelines of the *World Journal of Gastroenterology*, which recommends a title with no more than 12 words. We agree with the reviewer, that the new title is much more informative in regard to the content of the manuscript.

Modification in the revised manuscript:

“Golimumab in real-world practice in patients with ulcerative colitis: 12-month results **from a prospective, multicenter, non-interventional study in Germany**”.

Comment #2:

It is not very clear why the authors do not report the 24-month results that were presented at ECCO-2019 (https://academic.oup.com/ecco-jcc/article/13/Supplement_1/S337/5301088). It seems important as 24-month results not only show significant and clinically meaningful improvement, but also suggest a long-term (continuous) response to golimumab in terms of work productivity, activity and HRQoL in UC patients.

Response #2:

The reported 24-months results presented at ECCO 2019 based on the raw data (interim analysis) from a database snapshot dated 17-SEP-2018, i. e. containing results only for those patients for whom data were already available for a 2 year follow-up period. Study was still ongoing at that time. The final study report, which includes the complete 2 year data, is still in preparation. For this reason we decided to present the data for 1 year results, as they were already completely available.

Response to science editor:

Thank you for your helpful comments.

Comment #1:

You need to provide the grant application form(s) or certificate of funding agency for every grant, or we will delete the part of "Supported by...".

Response #1:

We uploaded the file "54575-Approved Grant Application Form(s) or Funding Agency Copy of any Approval Document(s)" with further information about the funding of this non-interventional study by MSD Sharp & Dohme GmbH, Haar, Germany.

Comment #2:

Please don't include abbreviations in the title of the figure/table. Please explain all the abbreviations in the figure/table legends as full name (abbreviation). Please explain all the abbreviations of each figure/table under each piece of figure/table legends. ...and for statistical significance, please use superscript letters.

Response #2:

We removed the abbreviations in the title of the figure/table and replaced them as follows (changes in bold). Additionally, we added the full name of all abbreviations in the figure/table legend (changes in bold) and explained all the abbreviations under each piece of figure/table legend (changes in italics). Statistical significance is applied in the figures and figure legends according to the scientific editor's comments (changes in bold).

1. Figure 1: Overview of mean **work productivity and activity impairment** (WPAI) domain scores comparison vs. baseline in patient employed at baseline (**employed analysis population, mITTe**). A: Patients with absenteeism; B: Patients with presenteeism; C: Patients' work impairment; D: Patients' activity impairment. Bars represent the standard deviation (SD). **A significant reduction in all WPAI subscores after onset of golimumab therapy was detectable for each time point in comparison to baseline (for each visit $p < 0.0001$, Wilcoxon signed rank test).**

WPAI: Work productivity and activity impairment; mITTe: Employed analysis population; SD: Standard deviation; n: Number of patients; BL: Baseline.

2. Figure 2: **Inflammatory bowel disease questionnaire (IBDQ) score** – change from baseline over time (**total analysis population, mITT**). **The difference from baseline in the total IBDQ score was statistically significant for all visits (^a: p<0.0001; Wilcoxon signed rank test). Standard deviation is given in brackets.**

IBDQ: Inflammatory bowel disease questionnaire; mITT: Total analysis population.

3. Figure 3: **Short Form-12 Health Survey Questionnaire-Physical Component Score (PCS-12) and Short Form-12 Health Survey Questionnaire-Mental Component Score (MCS-12)** – change from baseline over time (**total analysis population, mITT**). **The difference from baseline in the PCS-12 as well as in the MCS-12 score was statistically significant for all visits (^a: p < 0.0001; Wilcoxon signed rank test). Standard deviation is given in brackets.**

PCS-12: Short Form-12 Health Survey Questionnaire-Physical Component Score;

MCS-12: Short Form-12 Health Survey Questionnaire-Mental Component Score;

mITT: Total analysis population.

4. Table 1: Demographic and disease-specific properties

Data are shown as n (%), except where otherwise mentioned.

mITT: total analysis population; mITTe: employed analysis population.

5. Table 2: Occupational status

Data are shown as n (%).

mITT: total analysis population; mITTe: employed analysis population.

¹One subject who stated “retired” on the eCRF was included, because she had entries in the WPAI. It was assumed that this subject actually worked part-time.

eCRF: Electronic case report form; WPAI: Work productivity and activity impairment.

6. Table 3: Selected concomitant medications

Data are shown as n (%).

mITT: total analysis population; mITTe: employed analysis population.

Comment #3:

Please don't include any *, # in your manuscript

Response #3:

We checked the manuscript carefully for any * or #.

Comment #4:

Please use superscript numbers for illustration

Response #4:

We changed in Table 2: Occupational status footnote F¹ in ¹ (cf. Response #2, No. 5).

Comment #5:

For statistical significance, please use superscript letters.

Response #5:

We added superscript letters in our figures to indicate statistical significance.