Author's response to reviews

Title: Real-World Utilization Patterns and Outcomes of Colesevelam HCL in the GE Electronic Medical Record

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Version: 2 Date: 3 July 2013

Author's response to reviews: see over
Thank you for the opportunity to revise and resubmit this manuscript. We found the reviewer’s comments helpful and have revised the paper accordingly. Below is a point-by-point summary of our responses and/or revisions. We also have carefully reviewed the instructions for authors and believe the manuscript formatting is now more aligned with the Journal’s specifications.

Reviewer’s report: Referee 1

Version: 1

Date: 26 May 2013

Reviewer: Nicholas Tentolouris

Reviewer’s report:

Revisions: none

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: There is no financial or non-financial conflict of interest related to this work

Reviewer’s report: Referee 2

Version: 1

Date: 1 June 2013

Reviewer: cp ooi
Reviewer's report: Major Compulsory Revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English:

Editorial Comments

Reviewer: Abd Tahrani, Section Editor

I like the manuscript and I believe that it adds to our knowledge in the field. My comments are both statistics.

1) I would like the authors to report the 95% CI for the change in A1c.

   All of the standard errors in Tables 2-5 have been replaced with 95% confidence intervals.

2) Also, why did the authors use t test? Wouldn't it be more appropriate to use a repeated measure analysis?

   While we created three cohorts representing time intervals that corresponded with time intervals assessed in clinical trials, these cohorts were viewed as independent analyses and therefore the study design was not appropriate for repeated measures analyses. There were no between-subject effects to test, and within-subject effects were not an objective of this study.

3) Also the authors need to mention in the limitations as this is observational study based on a database, the change in A1c could be related to unmeasured factor such as weight change, so this cannot be ruled out.

   This is a great point, and we have added it to the limitations section.

4) Finally, was the change in A1c related to gender or age? Have the authors performed a subgroup or adjusted analysis (ANCOVA or linear regression) to explore the impact of age and/or gender?

   We did some limited exploration on the impact of age and gender, but the signals were mixed. For instance, in an ANCOVA model, gender was not significantly correlated with the change in A1C for the Week 16 ITT data, but age was. However, for the Week 26 ITT data, the reverse was true. Therefore, we have chosen not to do any further subgroup analyses than what is already presented. We have added this point, along with the above comment on weight, to the discussion.
Editorial requests:

1. Competing interests - Please include a 'Competing interests' section between the Conclusions and Authors' contributions. If there are none to declare, please write 'The authors declare that they have no competing interests'.

The questions that are asked of authors are:

Financial competing interests:
- In the past five years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.
- Do you hold any stocks or shares in an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? If so, please specify.
- Do you hold or are you currently applying for any patents relating to the content of the manuscript? Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript? If so, please specify.
- Do you have any other financial competing interests? If so, please specify.

Non-financial competing interests: are there any non-financial competing interests (political, personal, religious, academic, ideological, intellectual, commercial or any other) to declare in relation to this manuscript? If so, please specify.

We have moved our disclosure paragraph from the title page to a “competing interests” section following the conclusions. We also have reviewed this text to make sure it conforms with the guidance provided.

2. Authors' contributions - Please include an 'Authors' contributions' section before the Acknowledgements and Reference list.

For the Authors' contributions we suggest the following format (please use initials to refer to each author's contribution): "AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination. All authors read and approved the final manuscript."

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study. To qualify as an author one should 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; and 3) have given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support.
We have reviewed the Author’s Contribution section for accuracy and moved it from the title page to the section immediately following Competing Interests.

3. Acknowledgements? We strongly encourage you to include an 'Acknowledgements' section between the Authors contributions section and Reference list. Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include their source(s) of funding. Please also acknowledge anyone who contributed materials essential for the study. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements.

Please list the source(s) of funding for the study, for each author, and for the manuscript preparation in the acknowledgements section. Authors must describe the role of the funding body, if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

All people who made substantial contributions to conception, design, acquisition of data, and analysis and interpretation of data, as well as those who were involved in drafting the manuscript or revising it critically for important intellectual content are included as authors, and their respective roles are detailed in the author’s contributions section.

While it seems repetitive with the competing interests section, we have added the requested detail about sources of funding in an Acknowledgements section. While employees of the funder were authors on the study, no other agents of the funder contributed to the study design, analysis, interpretation of data, or writing of the manuscript. The decision to publish was the authors.

4. Please declare funding from Daiichi-Sankyo.

This is done in both the competing interests and acknowledgements sections.

5. Also, please clarify whether any permission was required for use of data.

This is now covered in the acknowledgements sections.