Author’s response to reviews

Title: Cost-effectiveness of insulin degludec versus insulin glargine U100 in adults with type 1 and type 2 diabetes mellitus in Bulgaria

Authors:

Monika Russel-Szymczyk (zmns@novonordisk.com; bmoore@dresources.com)
Vasil Valov (vasv@novonordisk.com)
Alexandra Savova (alex_savova@mail.bg)
Manoela Manova (manoela_manova@yahoo.com)

Version: 3 Date: 20 Nov 2019

Author’s response to reviews:

Dear Editor in Chief,

On behalf of my co-authors, please find below the point-by-point response to the editorial comments.

Technical Comments:
rename 'Data Availability' to 'Availability of data and materials'
remove duplicate Ethics approval and consent to participate statement
remove duplicate tables and figs in the ms.
Response: Implemented. We have removed the tables and figures from the manuscript body, so they are only available in the separate files now.

Assistant Editor Comments:
1. Overlap
   -- We note that the current submission contains some textual overlap with other previously published works, in particular:
   https://nam01.safelinks.protection.outlook.com/?url=https%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs13300-018-0426-0&data=02%7C01%7Cbmoore%40teamdrg.com%7C0%7C0%7C5d6495b15cd44a4af6dd15f3bf8831%7C0%7C0%7C6370974257492576855%7C0%7C0%7C5d6495b15cd44a4af6dd15f3bf8831%7C0%7C0%7C6370974257492576855%7C0%7C0%7C5d6495b15cd44a4af6dd15f3bf8831%7C0%7C0%7C6370974257492576855%7C0%7C0%7C5d6495b15cd44a4af6dd15f3bf8831%7C0%7C0%7C6370974257492576855&data=NhTD4iSLTo29C0vBCNsePdM8G%2BfkjGoOzwRziJZ60g%3D&amp;reserved=0
   This overlap mainly exists throughout your manuscript.

While we understand that this is work that you have previously published, and some of the same ideas are contained in these publications, please be aware that we cannot condone the use of text from previously published work.
If there is overlap in the Methods section, please ensure to summarize the methods and cite the source. Please rephrase these sections to minimize overlap.

Specifically:
Lines 19-37
Response: Modifications made where possible

Lines 70-83
Response: Modifications made where possible. Please note that we have not been able to modify the description of degludec any further without changing the meaning (lines 73-76).

Lines 88-130
Response: We have made changes where possible. Please note that there was no overlap in lines 99-104, and that we did not think it appropriate to modify the objective, lines 105-107. We also did not see an overlap in the model overview, lines 110-130. We do recognize that there are strong similarities with the model overview of Lalic et al. However, there are also a number of differences, which make it impossible for us to simply refer back to Lalic. A further summary of this section is also not possible without losing the overview. We consider it key to provide at least a simple and complete model overview, to allow the reader to understand the presented analysis.

Lines 137-154
Response: Insulin dose, line 137-142, has similar methods, but some different inputs and a table associated with it. Furthermore, one of the peer-reviewers had commented on this section, requesting a clarification, and we are therefore reluctant to modify the content at this point. We have attempted to modify the wording. Similarly, for the event rates, lines 144-154, the source data differ and do not allow us to simply refer back. We have implemented some wording changes, but are limited by the vocabulary of economic/statistic methods and conserving the meaning.

Lines 170-188
Lines 201-220
Response: Lines 171-172 are standard wording, which is generally used in any publication reporting an economic model that includes sensitivity analyses. Lines 175-188 are the results. The results (i.e. numbers reported) are different. For the wording, we are limited by the fact that this is based on the same model, but reports results for a different country. We can’t change the wording and yet remain precise, brief and to the point. The same applies to lines 201-220, the sensitivity analysis.

Lines 237-259
Response: We have applied changes to lines 237-244. For lines 245-254, these discuss the time horizon of the model, which is not discussed in Lalic et al. Lines 254-259 cite the results of the country models previously published.

Lines 281-304
Response: We reformulated lines 281-282. However, until 293, there is no clear overlap, although the content is similar, which is required to outline the clinical benefit of degludec, which leads to cost savings. Modifications have been made in lines 294-304 to remove any overlap.

Lines 310-316
Response: Flexible dosing is not discussed in this detail in Lalic. The utility gain has previously been
modified in line with peer reviewer comments, and we are therefore reluctant to modify it further. The content has some differences to Lalic, and the wording is different.

Lines 332-339
Response: The content of these lines (limitations) are standard content, which is not easily modified without changing the meaning. Although also used in other manuscripts, it is important to state.

2. Authors Contributions

-- Please include the individual role of each author, it is not sufficient to say;

All named authors (MR, VV, AS, MM) meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

-- Please include a statement in the Authors' contributions section to the effect that all authors have read and approved the manuscript, and ensure that this is the case.
Response: Implemented

3. Abbreviations

-- Please remove the abbreviations table and include these as text under the 'abbreviations' heading just before the declarations.
Response: Implemented

4. Funding

-- In the section 'Funding', please also describe the role of the funding body/bodies in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.
Response: Implemented

5. Additional Files

-- Please also add a section “Additional files” where you list the following information about your supplementary material:
- File name
- Title of data
- Description of data

Please ensure that all additional files are explicitly referred to in the main text.
Response: Implemented

6. Cite

-- Please ensure that all figures/tables and supplementary files are cited within the text. Any items which are not cited may be deleted by our production department upon publication.
Response: Thank you for the clarification.
Yours faithfully,

Monika Russel-Szymczyk
Novo Nordisk Sp. z o.o,
Ul. Krakowiaków 46
PL 02-255 Warsaw
Poland
zmns@novonordisk.com