



PMI RESEARCH & DEVELOPMENT

Corrigendum

FDA Question 21 included in RESPONSE TO AUGUST 4, 2017
INFORMATION REQUEST for MR0000059-MR0000061 and
AMENDMENT to MR0000059-MR0000061, 8 September 2017

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the provisions of applicable law. No part of this document may be publicly disclosed without the written consent of Philip Morris International Management S.A.

1 LIST OF ABBREVIATIONS

Abbreviations used in this document are consistent with those reported in the RESPONSE TO AUGUST 4, 2017 INFORMATION REQUEST for MR0000059-MR0000061 and AMENDMENT to MR0000059-MR0000061, 8 September 2017.

2 DEFINITION OF TERMS

Special terms used in this document are consistent with those reported in the RESPONSE TO AUGUST 4, 2017 INFORMATION REQUEST for MR0000059-MR0000061 and AMENDMENT to MR0000059-MR0000061, 8 September 2017.

3 RATIONALE

The Sponsor wishes to submit this Corrigendum to RESPONSE TO AUGUST 4, 2017 INFORMATION REQUEST for MR0000059-MR0000061 and AMENDMENT to MR0000059-MR0000061, 8 September 2017 for the following reason: after the response had been finalized and sent to the Office of Science, Center for Tobacco Products, at the Food and Drug Administration, the Sponsor noticed that there were some incorrect terms included in the text of the response to FDA Question 21.

4 CORRIGENDUM

4.1 Corrigendum to FDA Question 21, 8 September 2017

The following text at page 100 requires correction as follows (in bold below):

[...]

*The main result of this additional analysis is that the claims were associated with **larger** ~~smaller~~ differences in Perceived Health Risk scores between CC and THS compared to no claims, in all smoking status groups. This is consistent with the claim being successful in lower risk perceptions of THS relative to CC, however there was no reliable effect of claims on Intent to Use THS.*

[...]

The direction of the differences in Perceived Health Risk scores between CC and THS when comparing the ‘claims studies’ (i.e. the THS-PBA-05-RRC-US, THS-PBA-05-RRC2-US and THS-PBA-05-REC-US studies) and the no claims study (i.e. the THS-PMTA-05-NOC-US study) was incorrect.

Therefore, the correct wording for this paragraph should be what appears above in **bold**.

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Also, the following text at pages 102-103 requires the following corrections (in bold below):

[...]

*Considering the differences in Perceived Health Risk between CC and THS, there were **higher** ~~lower~~ levels for the claims studies compared to the no claim study in all smoking status groups (Table 20).*

*There were lower absolute levels of Perceived Addiction Risk for THS, for the claims studies compared to the no claim study, in Adult Former Smokers, Adult Never Smokers and LA-25 Never Smokers. Considering the differences in Perceived Addiction Risk between CC and THS, there were **higher** ~~lower~~ levels for the claims studies compared to the no claim study in Adult Never Smokers only (Table 21).*

[...]

The direction of the differences in Perceived Health Risk scores between CC and THS when comparing the ‘claims studies’ and the no claims study was incorrect.

Therefore, the correct wording for this paragraph should be what appears above in **bold**.

Finally, the following text at page 106 requires the following corrections (in bold below):

[...]

*In summary, this new analysis revealed that there were **higher** ~~lower~~ levels in the differences in Perceived Health Risk scores between CC and THS in the claims studies compared to the no claim study, in all smoking status groups. There were **higher** ~~lower~~ levels in the differences in Perceived Addiction Risk scores between CC and THS, in Adult Never Smokers but not in the other smoker status groups.*

The direction of the differences in Perceived Health Risk scores between CC and THS when comparing the ‘claims studies’ and the no claims study was incorrect.

Therefore, the correct wording for this paragraph should be what appears above in in bold

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5 APPROVAL

SIGNATURES OF SPONSORS RESPONSIBLE PERSONNEL

We, the undersigned, confirm that to the best of our knowledge this Corrigendum version 1.0, dated 09 November 2017 to FDA Question 21, included in the RESPONSE TO AUGUST 4, 2017 INFORMATION REQUEST for MR0000059-MR0000061 and AMENDMENT to MR0000059-MR0000061, dated 8 September 2017, accurately describes the experimental methods and results of the analysis conducted.

Signed: Pierpaolo Magnani
Pierpaolo Magnani
PBA Program Manager

Date: 15/NOV/2017

Signed: Felix Beacher
Felix Beacher, PhD.
Study Manager

Date: 15/NOV/2017

Signed: Gerd Kallischnigg
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Biostatistician

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