Author’s response to reviews

Title: Characteristics of Pediatric Adverse Drug Reaction Reports in the Japanese Adverse Drug Event Report Database

Authors:

Aoi Noda (a.noda@megabank.tohoku.ac.jp)
Takamasa Sakai (tksakai@meijo-u.ac.jp)
Taku Obara (obara-t@hosp.tohoku.ac.jp)
Makoto Miyazaki (makoto.miyazaki@merck.com)
Masami Tsuchiya (masami-tuchiya@miyagi-pho.jp)
Gen Oyanagi (gen.oyanagi@hosp.tohoku.ac.jp)
Yuriko Murai (y-murai@tohoku-mpu.ac.jp)
Nariyasu Mano (mano@hosp.tohoku.ac.jp)

Version: 3 Date: 30 Apr 2020

Author’s response to reviews:

Re: Manuscript ID: PHAT-D-19-00386R2

Manuscript title: Characteristics of Pediatric Adverse Drug Reaction Reports in the Japanese Adverse Drug Event Report Database

Editor Comments:

Thank you very much for your comment with regards to our manuscript. According to your comment, we revised our manuscript as follow. We hope that the manuscript has been sufficiently revised.

1. Please address Reviewer#2:

“I have no further comment, only a suggestion concerning the seriousness definiton. Looking at the author's reply and since medical devices are nor related to this paper, I suggest to replace the long sentence in page 8 row 137 "An adverse events was collected.....meets one or more of criteria from (1) to (7)" with the following: "Adverse events were considered serious when they
resulted in death, were life threatening, required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability or incapacity, were congenital abnormalities or birth defects or were any other medically significant events."

&gt; We responded to Reviewer#2’s comment.

2. Ethics approval and consent to participate

Please provide the status of consent to participate in this section. If no consent to participate was required due to the retrospective nature of this study, please also clarify this.

&gt; In accordance with your remark, we added some sentences in the ethics approval and consent to participate section as follow;

Page 18 line 379;

“No consent to participate was required due to the retrospective nature of this study.”

3. Funding

The role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript should be declared in this section.

&gt; In accordance with your remark, we revised some sentences in the funding section as follow;

Page 19 line 397;

“The design of the study was supported by the grant from the Ministry of Health, Labour and Welfare of Japan (H24-iyakuwakate-011). The interpretation of data, analysis, and writing the manuscript were supported by the grants from Research on Regulatory Harmonization and Evaluation of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics from the Japan Agency for Medical Research and Development, AMED (17mk0101095h0001, 18mk0101095h0002) and the Japan Society for the Promotion of Science (JSPS) (19K07213).“

4. Clean copy

Please ensure that when you upload your revised submission that it is in the final form for publication. Please remove any tracked changes or highlighting and include only a single clean copy of the manuscript. Should you wish to respond to these revision requests, please include the information in the designated input box only. Please remove ‘200413_cover letter.docx’ and ‘200413_Response to Reviewers comments.docx’ from the file inventory.
In accordance with your remark, we uploaded our revised manuscript that it was in the final form for publication.

Dr. Ugo Moretti (Reviewer 2):

Thank you very much for your valuable comment for our manuscript. According to your comment, we revised our manuscript as follow. We hope that the manuscript has been sufficiently revised.

1. I have no further comment, only a suggestion concerning the seriousness definition. Looking at the author's reply and since medical devices are not related to this paper, I suggest to replace the long sentence in page 8 row 137 "An adverse event was collected.....meets one or more of criteria from (1) to (7)" with the following: "Adverse events were considered serious when they resulted in death, were life threatening, required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability or incapacity, were congenital abnormalities or birth defects or were any other medically significant events."

In accordance with your remark, we revised some sentences in the methods section as follow:

Page 8 line 137;

“Adverse events were considered serious when they resulted in death, were life threatening, required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability or incapacity, were congenital abnormalities or birth defects or were any other medically significant events.”