Author's response to reviews

Title: Estimating time-to-onset of adverse drug reactions from spontaneous reporting databases

Authors:

Fanny Leroy (fanny.leroy@inserm.fr)
Jean-Yves Dauxois (jean-yves.dauxois@insa-toulouse.fr)
Hélène Théophile (helene.theophile@pharmaco.u-bordeaux2.fr)
Françoise Haramburu (francoise.haramburu@pharmaco.u-bordeaux2.fr)
Pascale Tubert-Bitter (pascale.tubert@inserm.fr)

Version: 2 Date: 16 October 2013

Author's response to reviews:

Dear Editor,

Please find enclosed the revised version of our manuscript entitled "Estimating time-to-onset of adverse drug reactions from spontaneous reporting databases" that we submitted for publication in BMC Medical Research Methodology.

As the French pharmacovigilance database is not publicly available, we clarified the authorization details for data access.

On page 7 of the manuscript, just before the "Results" section, we replace the third paragraph "The French pharmacovigilance database is maintained by the French drug agency (Agence Nationale de Sécurité du Médicament et des produits de santé) and is not publicly available. It is build up and used on an ongoing basis by the regional pharmacovigilance centres. The present study was conducted on data extracted by the Bordeaux regional pharmacovigilance centre." by the following paragraph: "The French pharmacovigilance database is developed by the French drug agency (Agence Nationale de Sécurité du Médicament et des produits de santé, ANSM) and is not publicly available. It is build up and used on an ongoing basis by the network of regional pharmacovigilance centres, which have a direct access to the data. This set of data has already been extracted for another study [25] with the authorization of the ANSM and the network of regional centres, according to the internal rule."

We hope that you will find these changes adequate.

Sincerely yours,

Fanny Leroy