Reviewer's report

Title: Designing concept maps for a precise and objective description of pharmaceutical innovations

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Reviewer: Fabrizio De Ponti

Reviewer's report:

This paper deals with a topic of great interest for drug developers and regulatory agencies (and, of course, for patients).

I appreciate the authors’ effort to consider the clinical perspective, building on previous experience in several countries.

I have reviewed the manuscript after a first review by two independent reviewers, and I must say that I agree with most of the suggestions of the previous referees. Unfortunately, a covering letter with a point-by-point outline of the responses to the issues raised by the referees was not provided to me.

My impression is that the authors have disregarded most of the key suggestions. In particular, I agree with Dr Cheng in saying that the paper needs more focus on the process for how the concept maps were developed and tailored to physicians, with specific examples of challenging drugs, disagreements between the authors and processes to resolve disagreements. The authors say that the model was developed using a training set of 40 drugs and then "validated" with a test set of 20 drugs. Formally, this cannot be considered a validation unless the authors provide full details of the entire process (this can easily be achieved with supplementary online material detailing the process for the 60 drugs that were analysed in the whole process). How was the Delphi-like approach applied in every circumstance to resolve disagreements?

In conclusion, this is the only issue that requires major, compulsory revision, all the more so because the manuscript is submitted to a journal of medical informatics.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

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

Declaration of competing interests:

I declare that I have no competing interests