Reviewer’s report

Title: Scarce quality assurance documentation in major clinical trial registries for approved medicines used in post-marketing clinical trials

Version: 0 Date: 02 Dec 2018

Reviewer: Celine Caillet

Reviewer's report:

This paper is a crucial piece for public health and is well written, easy to understand. The authors have discussed on a crucial issues found in Phase IV trials, based on a concrete assessment of CTR and I hope this paper will be largely communicated to advocate for a change in regulation.

Key messages are well written and understood and I have no major comment to make.

I only have one minor comment:

In the Background (second page) L11-13: 'in infants'

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Please indicate the quality of language in the manuscript:

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