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: 21 Nov 2018

Reviewer: Paul Newton

Reviewer's report:

An interesting paper on an important but neglected subject.

Background

a/ Suggest to refer to WHA 2017 definitions of medicine quality - substandard and falsified. Degraded are included in substandard category in these definitions

b/ the last sentence of the penultimate para of first page of Background seems incorrect. DRAs are also key for addressing falsified medicines

c/ use of term 'substandard quality' is confusing in relation to the WHA 2017 substandard category - suggest to use the term substandard and falsified that is what reference 8 referred to

d/ my understanding from reference 16 is that the clopidogrel was not used in 2007 as an IMP - it was thankfully detected before it could be used. Suggest to change

e/ Page 7, line 32 - not clear to me who suggested this previously?

f/ I could not see mention of CONSORT guidelines - feel that they should be included

References

Ref 18, 20, 21, 23 need a web page address

Box 1 - should the product Lot Number be given too?

Should mention be made explicitly of vaccine quality for vaccine trials?

The paper could be shortened
Level of interest
Please indicate how interesting you found the manuscript:

An article of importance in its field

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