Reviewer’s report

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

Version: 1 Date: 05 Jan 2019

Reviewer: Paul Newton

Reviewer's report:

The ms has been improved but two aspects remain in need of attention:

Page 7 - line 52 'While solely falsified medicines are addressed by law and security enforcement authorities, all three types of SF medicines are assessed by drug regulatory authorities (DRAs) based on criteria determining their quality as shown in Box I.'

is not correct

Suggest edit to:

All three types of SF medicines are assessed by drug regulatory authorities (DRAs) based on criteria determining their quality as shown in Box I. Falsified medicines especially will need involvement of law and security enforcement authorities'

Soley is not correct as law enforcement is also potentially relavent to substandard and unregistered medicines

Page 9, line 19 :

'The CONSORT guidelines were followed for the reporting of this study.'

This is incorrect - please see the CONSORT guidelines that are for reporting clinical trials and not for reviews

In my original note I was referring to the comment in reference 16 that CONSORT should include description of the quality of medicines used in clinical trials
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