Reviewer’s report

Title: Comparison of Serious Adverse EventsPosted at ClinicalTrials.gov and Published in Corresponding Journal Articles

Version: 1 Date: 27 May 2015

Reviewer: Andrew Jull

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Major compulsory revision

1. The purpose of the paper is unclear, which is related to objectives not being clearly identified in the abstract. Is the purpose to examine the effect of the legal requirements in 2009, or is it to examine compliance with those legal requirements to publish SAEs on ClinicalTrials.gov since 2009? Or perhaps some other purpose is intended? It is difficult to judge the paper without understanding what was the intended purpose.

2. The conclusion at the end of the paper differs somewhat from that in the abstract and suggests that part of the solution to under-reporting is to advocate for mandatory posting of results to all countries. However, that does not seem to have worked in the US and thus why should it have an effect elsewhere?

Minor essential revisions

1. In figure 1, it would make more sense to report the number not phase 3/4 trials before those with no serious adverse events reported. That way the reader could understand the number of phase 3/4 trials that did not post SAE data.

2. In the random sample there were still 30 out of 202 trials (figure 3) that did not post SAEs, despite these supposedly being screened out in earlier screening processes - how did that occur?

3. It is not clear why 300 was the selected sample size for the random sample

4. It would be useful to indicate why trials comparing a drug to a device were excluded and to report that exclusion in figure 1.

5. Might it be useful to describe the 33 trials that had posted the same number of SAEs on ClinicalTrials.gov and their papers on selected characteristics? ie phase, funding source, discipline.

6. A key finding surely from figure 2 is that fewer than 10% of trials published their results on ClinicalTrials.gov within the required 12 month timeframe (although that may be influenced by when the trial was conducted ie pre-2007)

Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.