Reviewer's report

Title: Risk proportionate clinical trial monitoring: an example approach from a non-commercial trials unit

Version: 4 Date: 2 December 2013

Reviewer: Charlie Goldsmith

Reviewer's report:

There are still some suggestions that I think should be dealt with by the authors:
1. However, there are now some examples added as appendices. This means that there are now two lists of short forms and indeed many short forms are NOT listed in either of them: CRB, AE, CFQ, EQ5D, CV, DMA, HTA, ISF, CTIMP, QALY, LREC, R&D, RSA, TMF, IP, DSUR, DMP, PDR, SDV, HoS.
2. The R(eference)s have URLs that are NOT dated for date of last access: 5, 6, 13.
3. The appendix pages are not numbered to these items will need to searched to find them: Replace [regime] with [regimen].
4. (Appendix) 1, ?first page uses a different date format to the rest of the pages. Each of A2 seems to use a different date at the bottom of each page.
6. Suggest including a date format on all signoff sheets such as yyyy-mm-dd or another one that has a date format included.
7. There is at least one more [and/] that should be deleted.
8. Data seems to be treated as a singular word in various places where [is] should be [are].

Sorry for the delay. However, I have been given many more manuscripts than I have time to review in a timely manner.