Reviewer’s report

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

Version: 4 Date: 2 October 2013

Reviewer: Oana Brosteanu

Reviewer’s report:

The authors have answered to all points addressed. However, some concerns remain.

- Major Compulsory Revisions

1. Risk assessment:

The authors have added a short description of the risk assessment procedure, and state that they purposely do not explain the scoring system, since risk assessment is not in the main focus of the paper. I understand this point, but my concern is that the risk assessment template, which is meant as an example, will nevertheless be used by future readers. Thus, in my opinion it is necessary to explain in more detail how to use it. In particular, the following aspects should be covered:

What are the provisions if a trial has overall a low risk, but there is one or more risk category with a high (>10) or even very high (>=20) score? Why on the first page of the risk-assessment only the mean score is mentioned and not the maximum score?

- Minor Essential Revisions

2. In the diagrams in Figure 4, the y-axis is labeled, but the respective scale is still missing.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests