Comments from a contributor who wishes to remain anonymous

I am writing in response to the above consultation, with a couple of operational points.

- The guidance is very comprehensive and easy to understand however I wondered whether this might be combined with the clinical study report to avoid non-commercial teams having to provide two fairly lengthy documents containing similar information. If end of study report were a lay report it would be an advantage in many ways even if it were optional (i.e. Sponsors could decide if they wanted to write two reports, one technical and one lay, or combine into one depending on the complexity of information).

- I was not clear from the guidance ***how*** to undertake the literacy test and whether this was something we might be later inspected on. If Sponsors might be asked to evidence the test then it would be helpful to provide additional information and links in the guidance document on how to practically go about undertaking them.

My apologies if this was already in the document or I have misunderstood the nature of the reports. I would be very happy to discuss further. Please note that I am sending this response from a personal perspective and not on behalf of my organisation.

With very best wishes