Reviewer's report

Title: Measuring patient reported outcomes: Moving beyond misplaced common sense to hard science

Version: 4 Date: 25 April 2011

Reviewer: Stephen Joel Coons

Reviewer's report:

A number of the concerns I had with the earlier version of the manuscript have been addressed; however, some important concerns remain unaddressed/uncorrected. Although I don't agree with everything asserted in this manuscript, the author is making some substantive points about the conventional wisdom in PROM development and/or adaptation that needs to be challenged so that truly informed and constructive debate can occur.

Major Compulsory Revisions

1. Page 2, para 3: The author states, “To summarise, PROMs that assess symptoms (impairment) or functional limitations (disability or activity) address issues of primary interest to the clinician.” This statement implies that these concepts are not of primary interest to patients, which is not the case in many situations (e.g., severe pain, inability to use toilet without help). I truly believe that the author is making a false distinction here. The clinician is likely to focus on symptoms and functional impairment because those are likely the most proximal/tangible target of clinical interventions. Too many other factors affect a person's quality of life that are outside of the clinician's control.

2. Page 7: The following statement is not true: “Indeed, this measure has such poor psychometric properties that it has never proved to be a valuable instrument for showing differences between active treatments.” I asked that it be corrected in my earlier review. Please see: http://www.thyrogen.com/pdfs/pi.pdf

3. Table 1. I do not see how “Utility” is considered a type of PRO measure. There are preference/utility elicitation exercises (e.g., SG, TTO) that are used to derive value sets that can be applied to the results of self-reported health states on preference-based HRQL measures; however, I know of no PRO measures that directly assess “utility” as a patient-reported outcome. This requires further clarification and an example of such a measure. In the second paragraph under “What do PROMs measure?” on page 2, the author does not even mention “utility” as an example of a PROM.

4. Figure 3. I am still at a loss as to what this figure is truly depicting and how it helps the reader understand the “Current usage of PRO outcomes in medical research.” In addition, I don’t think the title of the figure should refer to patient-reported outcome (PRO) outcomes.
5. Text box 2: There are entries in this table that should be supported with balanced evidence from the scientific literature (e.g., “Simple 2-point response formats are preferable to multiple response formats”). In addition, several statements are inaccurate. For instance, the EQ-5D is not a “utility” measure.

6. Appendix: The statement that “Content for all PRO scales should be derived from interviews with relevant experts or patients” is not consistent with earlier assertions by the author (e.g., text box 1: “QoL scales should be derived from interviews with relevant patients”) that patients’ concerns/issues are paramount. Hence, the word “or” is inappropriate in that sentence since interviews with “relevant experts” are not sufficient.

Minor Essential Revisions

7. Text box 1: It appears that references are still needed.

8. Page 6, last sentence: Replace "Drink" with "Drug" (i.e., US Food and Drug Administration).

9. Abbreviations: Same as above. The FDA is the Food and Drug Administration, not the Food and Drink Administration.

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 I have no competing interests.