Reviewer's report

**Title:** Quality-of-life evaluation for advanced non-small-cell lung cancer: a comparison between vinorelbine plus gemcitabine followed by docetaxel versus paclitaxel plus carboplatin regimens in a randomized trial: Japan Multinational Trial Organization LC00-03 (BRI LC03-01)

**Version:** 2  **Date:** 23 June 2011

**Reviewer:** James Grutsch

**Reviewer's report:**

**OVERALL REVIEW**

Ideally this data should have been published in the original JCO article of several years ago. The authors, however, provide a convincing narrative of why that did not happen. Overall, these authors provide a case study of the value of Patient Provided Outcomes for clinical trials.

In this clinical trial no survival benefit was found, these authors however found that one treatment arm had a significant benefit in Quality of Life. The report that a specialist tool the FACT-taxane demonstrated that one arm of the trial should a statistically and clinically significant decline in quality of life. In addition the FACT-G instrument reported a large decline in the patient's capacity to fulfill activities of normal life.

**Quality of written English**

This is a very short manuscript that is readable. However, I would make two minor modifications

In the discussion section of the manuscript I would make two minor revisions in the language

1. Replace the sentence “However, the VGD group showed almost a level-off regardless of the time passage…. ” With something like “Patients in the VGD arm showed no significant variation over time in their quality of life scores, while the patients in the PC arm showed a steady decline in FACT-G and FACT-Taxane scores over time.”

2. Eliminate the last paragraph in the discussion and replace the first sentence in the next to last paragraph in the discussion with something like" This was a well designed and executed randomized clinical trial, but the Quality of Life portion of the trial had these limitations.”

**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