

Many thanks for sending the ACD for comment.

SHTAC has identified a few points which may need clarification:

1. In sections 3.7 to 3.10, CPB7.5 should read CPB7.5+.

2. In section 3.9, the following text seems to imply that the groups were compared with each, and also it does not take into account that the HRs for two of the analyses show non-significant effects:

"These analyses showed that the stage III patients with optimally debulked cancer derived a smaller improvement from the treatment (difference in median PFS of 1.6 months based on CP 17.7 months (n=368) and CPB7.5 19.3 months (n=383); HR 0.89, 95% CI 0.74 to 1.07) compared with stage III patients with suboptimally debulked cancer (difference in median PFS of 5.8 months based on CP 10.1 months (n=154) and CPB7.5 16.9 months (n=140); HR 0.67, 95% CI 0.52 to 0.87) or stage IV cancer (difference in median PFS of 3.4 months based on CP 10.1 months (n=97) and CPB7.5 13.5 months (n=104); HR 0.74, 95% CI 0.55 to 1.01)." (p.9)

3. Also in section 3.9 it is also not clear what is meant by the following text:

"No statistical tests of interaction were presented by the manufacturer for these subgroup data." (p.9)

4. In section 4.10 the following sentence implies that PFS in the chemotherapy arm in the ICON7 trial ITT population was worse than in the chemotherapy arm of the GOG trial in the ITT population (censored data), but it was not (ICON7 17.4 vs GOG 12). It was only worse when comparing the 'high risk' subgroup from ICON7 with the GOG censored ITT analysis (ICON7 10.5 vs GOG 12):

"The Committee also noted that PFS in the chemotherapy comparator arm was worse in ICON7 than in GOG-0218, which could affect interpretation of the results." (p.22)

5. In section 4.11, the difference in median PFS for the ICON7 high risk subgroup should read 5.5 months. (p.22)