Minutes for the Meeting of the SGCTG Statistics Group

June 6th, 2006, Atlanta

Present: Rene DuPont, Anne Marie, Jim Paul, Val Gebski, S. Pignata, Mark Brady, Elizabeth Eisenhauer

Apologies: Corneel Coens

1.   Randomisation Update

The following randomisation approaches were used by the groups:-

ANZGOG: Depending on study sometimes use minimisation and sometimes random permuted blocks

NCRI/MRC: Use minimization incorporating a random component.

GOG: Use minimization, but don't incorporate site as a factor, because in their setting it is often meaningless

NCIC: Use minimisation and usually incorporate centre as a factor, but adopt a pragmatic approach depending on the study.

SGCTG: Use minimisation and usually incorporate centre as a factor.

The recent criticism by the EMEA of minimization and its preference for random permuted blocks was discussed.   This was felt not to be particularly well founded and both methods have their advantages and disadvantages.   In particular the predictability of minimization within a centre could be addressed by incorporating a random factor (Statist. Med. 2005; 24:3715–3727).

It was not felt that a formal response to the EMEA from this was required as this had been taken up by others. Similarly there was no need for groups to change their existing practices, but be aware that issues may arise with regulatory bodies.

2.   CA-125 and surrogate end-points for treatment outcome

Mark and Elizabeth had made a recent presentation to the FDA on the topic of "End-points for regulatory approval" and would circulate this to the group.

There is good evidence in the first-line setting that pfs is a good surrogate for survival, but this predates the incorporation of CA125 into the definition.   Mark and Elizabeth intend to revisit this using data form NCIC and GOG and establish what effect, if any, the new CA125 definition has had on this relationship.

In second-line the evidence that pfs is a good surrogate end-point, either for clinical benefit or survival is not so clear.   We agreed to review our trials with a view to putting together a data set to address this question.

Date of next meeting: October 2006 Santa Monica IGCS