

Minutes of the GCIG statistics meeting, 29 may 2008, Chicago.

Attendees: Mark Brady (GOG), Katryn Winther (RTOG), Jim Paul (SGCTG), Val GebSKI (ANZGOG), Alexander Reuss (AGO), Garnet Anderson (?), René dePont (NSGO).

A new facilitator Mark Brady and co-facilitator Katryn Winther, where elected.

The stat group should function as a think tank, addressing common problems and issues of both methodological as well as operational character. We identified and discussed various subjects of interest for future work:

- Unblinding
- QOL analysis
- ITT and ineligible patients
- The timing of release of results
- PFS definition, censoring acceptability as primary end-point. Treatment interruptions and the duration of these, sensitivity analysis. SAP preparation if monitoring or partially unblinded
- Non-inferiority trials, design and analysis
- Randomized phase II

Before each group meeting one member prepares a presentation on a subject on the list. The list is also revised.

Topic Liverpool: Unblinding(Jim)

Topic Orlando : Non-inf analysis (Val)

We briefly discussed DMC charters, these should not be too restrictive but gyne specific. Discussion and adaptations should be conducted for each new charter. Val will give more input on this pending the release of the Australian guidelines.

25 OCT 2008

René dePont