



GCIG Harmonization Committee - Statistical Section
5.30-6.30pm, May 30, 2013
Huron Room, Doubletree Hotel, 300 E.Ohio Street, Chicago

MINUTES

Chair: Jim Paul (james.paul@glasgow.ac.uk) - SGCTG

Co-Chair: Byung Ho Nam (byunghonam@ncc.rc.kr) – KGOG

Present:

Andrew Embleton (a.embleton@ctu.mrc.ac.uk) – MRC/NCRI;

Mark Brady (brady@gogstats.org) – GOG;

Alexander Reuss (Alexander.reuss@kks.uni-marburg.de) – AGO

Ji Zhu - SGOG --- Shanghai Gyne Oncology Group, China

Welcome & Introductions (C.O.I. declaration)

No conflicts of interest were declared.

1. Allowing/adjusting for treatment cross-over after progression in assessing effect of a new treatment on OS (Tetsutaro/Paul)

JP presented a slide set on this topic prepared by Tetsutaro Hamano (GOTIC/JGOG). Slide set attached.

Two main approaches were covered:-

- Inverse-probability-of-censoring weighting (IPCW)
- Rank-preserving structural failure time model (RPSFTM)

Both methods have significant problems in terms of model assumptions.

There was some experience in the group of the use of IPCW, but it was not felt that either method could be strongly endorsed. If IPCW was to be used it was recommend that that the model built for predicting switching be done separately/blinded from the treatment comparison.

2. Consensus on approaches to phase III trials for rare tumours - review of document prepared following 2011 GCIG meeting in Chicago (Brady)

There wasn't time for this item following the earlier talk and this was carried over to the next meeting.

3. Proposals for discussion topics at future meetings:

- a) The PFS/OS endpoint controversy for phase III trials (Brady)
- b) The use of futility boundaries in clinical trials (Brady)
- c) Response adaptive designs

4. AoB None