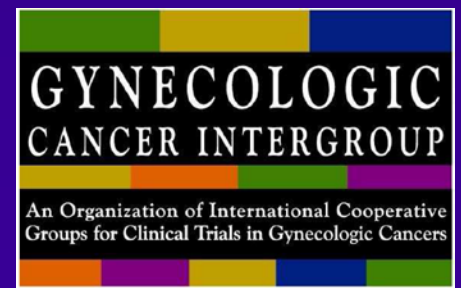


GCIIG Harmonization Committee Stats Section
Chicago, December 2014

General Assembly Report

Chair: Jim Paul, SGCTG

Co-Chair: Byung Ho Nam, KGOG

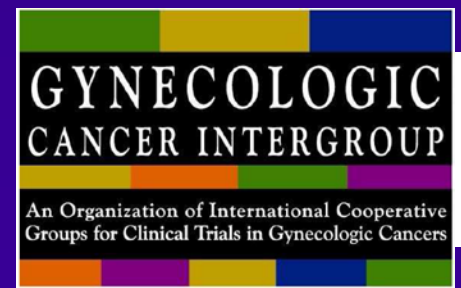


- Statistical Issues in Scanning to Assess Progression
 - Regulatory guidance (Byung Ho Nam)
 - Literature review (Alexander Reuss)
- Finalisation of position paper on phase III study designs for rare tumours
- Discussion topics for futures meetings:-
 - The merits of PFS or OS as primary end-point
 - Futility boundaries
 - Response adaptive designs
 - Approaches for non-proportional hazards
 - Issues around making data for GCIG trials routinely available for meta-analyses



Initial Conclusions re Scanning for Progression

- Frequency
 - Ideally same in both arms
 - Frequency can be half the median pfs in control arm without significant impact on power
 - Frequency can be different in different countries, as long as it still meets these first two criteria
- Central review
 - Literature/experience suggests this makes little difference
 - Not required for blinded studies our studies with large effects



Initial Conclusions re Scanning for Progression

- Analysis has inherent problem that we don't know exact time of progression
- Analysis further complicated by:-
 - Scan missed because of site/patient lack of compliance
 - Patients being switched to other anti-cancer treatment before progression
 - Patients coming off study therapy early before progression
- Variety of ways of dealing with these (no single correct approach)
 - Have to analyse the data in a number of ways (sensitivity analysis) to ensure conclusions are robust
- Will produce guidance document on this

