GCIG Harmonization Committee Stats Section

Chicago, December 2014

General Assembly Report

Chair: Jim Paul, SGCTG
Co-Chair: Byung Ho Nam, KGOG

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- 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

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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

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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 of 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

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