



**Harmonization Committee Statistical Section  
Saturday, December 1, 2012, 3:30pm – 5:30pm  
Wassenaar Room, Holiday Inn, Leiden**

**AGENDA**

**Chair: Jim Paul**

**Co-Chair: Byung Ho Nam**

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

1. Approaches to the design of phase II trials of targeted agents
2. Consensus on approaches to phase III trials for rare tumours - review of document prepared following 2011 GCI meeting in Chicago
3. Proposals for discussion topics at future meetings:
  - a. The PFS/OS endpoint controversy for phase III trials (Brady).
  - b. Dose intensity (Reuss).
  - c. The use of futility boundaries in clinical trials (Brady)
4. AoB