



HARMONIZATION COMMITTEE

Saturday, December 1, 2012

Holiday Inn, Leiden

AGENDA

1:00-3:00 PM Gouda Room

Operations /Data Management and Stats

1. **Welcome and Introduction:** Bryce (MITO) and Stonebraker(GOG)
 - Minuter:** Stonebraker
 - New members**
 - Conflicts of Interest (COI) declarations**
 - Additions to agenda**

2. **Approval of minutes – May 31, 2012**

3. **Website – (NB: Harmonization page)** Bacon for Easley

4. **Ongoing business**
 - a. **Group contacts and summaries** Martyn
 - b. **Tumour Banking checklist** (consent vs. actual) Negrouk & LeFur
 - c. **Nursing studies** Bryce
 - d. **QoL instruments** (move to SB liaison) for Winter
 - e. **Mentoring** (welcome package/on-line tutorial) Nepote

5. **New business:**
 - a. **Quality Assurance subcommittee report** Bryce & Stonebraker

b. Rare Tumours initiative (Regs. & Ops. & Stats.)

6. GCIG studies (lead group only)

3:30-5:30 PM Gouda Room

Operations/Data management issues:

1. Ongoing Business

- a. Common data elements revisited Bacon & Stonebraker
- b. Agreement template stats for Carty
- c. Translation Research committee liaison report for LeFur
- d. Symptom Benefit working group liaison report (& QoL)

2. Group Specific Appendix (GSA) minimum requirements Farrelly

3. Pharmacovigilance requirements, lead group Farrelly, Bryce

4. Roadmap ENGOT Votan

5. CCRN update Bacon & Martyn

6. European Directive updates, if any Negrouk

3:30-5:30 PM Wassenaar Room

Harmonization Statisticians group:

Ongoing business

New business