



HARMONIZATION COMMITTEE

Thursday, May 30, 2013

Doubletree Hotel, 300 E. Ohio Street , Chicago

AGENDA

3:30-5:30 PM State Room

OPERATIONS AND STATISTICIANS

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

2. **Approval of minutes – Dec 1, 2012**

3. **Harmonization: Ops/Stats overview-** Bacon & Brady

4. **Website and Harmonization page** Bacon & Hess
Revisions and updates; trials list; bibliography; roster; etc

5. **Ongoing Business**
 - a. **Group contacts and summaries** Martyn
 - b. **Guidebook** Carty
 - c. **Mentoring** Nepote
 - d. **Quality Assurance** Bryce & team

6. New Business:

- a. Rare Tumours working group brainstorming(Nov.2013)Bacon, Paul, Votan
- b. Approaches to data collection on international trials
- c. Response and progression evaluation issues

7. GCIG studies

- a. Nursing studies
- b. Lead group issues

8. AOB

9. Adjourn

5:30 to 6:30 pm State Room

Operations/Data management :

1. Ongoing Business.

- a) **Agreement template** status Carty (Negrouk, Votan, LeFur)
- b) **Group Specific Appendix (GSA) minimum requirements** Farrelly
(incl. Pharmacovigilance)
- c) **Translation Research committee liaison report** LeFur, Negrouk
(incl. Tumour Banking checklist)
- d) **Symptom Benefit working group liaison report (& QoL)** Martyn
- e) **Lead group matrix activity (participation)** for Martyn
- f) **CCRN update** (incl. Comments from reviewers) Bacon & Martyn
- g) **ENGOT liaison report** (incl. ROADMAP) Elser

2 New Business :

- a. **Insurance / Indemnity**
- b. **Site staff – German law** Polleis
- c. **Trial closure letters** Stonebraker

3 European Directive updates, if any Negrouk

4 AOB

5 Adjourn

5:30 to 6:30 pm Huron Room

Statisticians:

Chair: Jim Paul

Co-Chair: Byung Ho Nam

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

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

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

3. Proposals for discussion topics at future meetings (All)
 - 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)
 - d. Response adaptive designs

4. AoB