



HARMONIZATION COMMITTEE
Saturday, November 16, 2013
UCL Education Centre, London, UK

*****Please sign attendance sheet*****

AGENDA's

3:30-5:30 PM Clinical Skills 3 Room

Operations/Data management

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 – May 2013**
3. **Ongoing Business.**
 - a) **Agreement template** status Carty (Negrouk, Votan, LeFur, Gower)
 - 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)** Martyn

f) **CCRN update** (incl. Comments from reviewers) Bacon & Martyn

g) **ENGOT liaison report** Elser

4. **New Business :**

a. **Insurance / Indemnity** Polleis (Berger, Keller)

b. **Site staff – German law** Polleis

c. **Trial closure letters** Stonebraker

d. **Risk based monitoring** Farrelly , Negrouk

5. **European Directive updates, if any** Negrouk

6. **AOB**

7. **Adjourn**

5:30 to 6:30 pm Clinical Skills 3 Room

Operations and Statisticians

1. **Welcome and Introduction:** Bryce (MITO) and Paul (SGCTG)
 - Minuter:** Stonebraker
 - New members**
 - Guests**
 - Conflicts of Interest (COI) declarations**
 - Additions to agenda**
2. **Approval of minutes – May 2013**
3. **Website and Harmonization page** Powers (for Hess)
 - Revisions and updates; trials list; bibliography; roster; etc
4. **Ongoing Business**
 - a. **Group contacts and SUMMARIES** Martyn
 - b. **Guidebook** Carty
 - c. **Mentoring** Nepote (Hiltz, Aotani, Stonebraker)
 - d. **Quality Assurance** Bryce & team
5. **New Business:**
 - a. **Rare Tumours working group brainstorming report debriefing** Paul, Votan
 - b. **Approaches to data collection on internet'l trials** Brady (Polleis, Embleton)
 - c. **Response and progression evaluation issues** Bryce / Paul
 - d. **Risk-based monitoring** Farrelly & Negrouk
6. **GCIG studies**
 - a. **Nursing studies**
 - b. **Lead group issues**
7. **AOB**
8. **Adjourn**

Sunday, November 17, 7:00am – 9:00am

Room 5, UCL Education Centre

Statisticians

Chair: Jim Paul

Co-Chair: Byung Ho Nam