



GCIG HARMONIZATION COMMITTEE

Jikei University, Tokyo

Please sign in on attendance sheets

Tuesday, Nov.10, 2015, 9:00am – 11:00am -- 5F Room

Operations/Data Management:

Stonebraker (Chair)

Votan (co-Chair)

Bryce (past-Chair)

AGENDA

Welcome and Introduction:

Minuter:

New members:

Guests:

Conflicts of Interest (COI) declarations:

Additions to agenda:

Approval of Minutes/Report: May 2015

New Business :

- a) Budgeting in Intergroup trials** (Farrelly (overview and costing), Chavez (templates), Martyn (survey results))
- b) Communication in Intergroup trials** (Neven (ENGOT model) , LeFur, Kirkegaard)

Ongoing Business

- a) Group Specific Appendix status** Farrelly (Hiltz)
- b) Agreement** Votan (for Carty, LeFur)
- c) Lead group matrix activity (participation)** Martyn
- d) Insurance/indemnity** Polleis (Keller, Berger)
- e) Trial Closure Letters** Stonebraker

- | | |
|---|-------------------------------------|
| f) Group contacts and summaries | Keller (Hiltz) |
| g) Guidebook
Update of 05/27/15 mailing | Blattler & Kirkegaard |
| h) Mentoring | Nepote (Aotani, Hiltz, Stonebraker) |
| i) Essential documents | Sapetto-Rebow (Powell, Berger) |
| j) ENGOT liaison report
European Directive Update | Elser |
| k) OTHER | |

AOB

Adjourn

Wednesday, Nov.11, 2015, 8:00am – 10:00am -- 5F Room

JOINT: OPERATIONS AND STATISTICIANS

Stonebraker (Ops) Nam (Stats)

AGENDA

Welcome and Introduction:

Minuter:

New members:

Guests:

Conflicts of Interest (COI) declarations:

Additions to agenda:

Approval of minutes/report – May 2015

Website and Harmonization page

Cummings

Liaison reports:

Exec-BoD

Bryce/Nam

Ovarian Cancer Committee

Carty/Embleton

Endometrial Cancer Committee

Adema/Tu

Cervix Cancer Committee
Translational Research Committee
Rare Tumours working group
Symptom Benefit working group
Phase II working group
CCRN

Hiltz/Reuss
LeFur/Brady
Votan/Nam
Martyn/GebSKI
Blattler/Paul
Stonebraker

Ongoing Business:

Publication status
Quality Assurance

Votan, Martyn, LeFur, Carty
Bryce/Stonebraker

GCIG studies
a. Lead group issues

New Business:

AOB

Adjourn