



final

## **GCIG HARMONIZATION COMMITTEE**

Crowne Plaza Hotel, Melbourne

***Please sign in on attendance sheets***

**Wednesday Nov 5, 2014, 3:00pm – 5:30pm -- Bridge 2 Room**

**Operations/Data management :**

### **AGENDA**

**Welcome and Introduction:** Bryce (MITO) and Stonebraker(GOG)

**Minuter:**

**New members:**

**Guests:**

**Conflicts of Interest (COI) declarations:**

**Additions to agenda:**

**Approval of Minutes: May 2014**

#### **Ongoing Business.**

- |  |                                     |
|--|-------------------------------------|
| <b>a) Group Specific Appendix status</b>             | Farrelly (Hiltz)                    |
| <b>b) Lead group matrix activity (participation)</b> | Martyn                              |
| <b>c) Insurance/indemnity</b>                        | Polleis (Keller, Berger)            |
| <b>d) Trial closure letters</b>                      | Stonebraker                         |
| <b>e) Group contacts and summaries</b>               | Keller (Hiltz)                      |
| <b>f) Guidebook</b>                                  | Blattler                            |
| <b>g) Mentoring</b>                                  | Nepote (Aotani, Hiltz, Stonebraker) |

- |                         |                             |
|-------------------------|-----------------------------|
| h) Quality Assurance    | Bryce (Martyn, Stonebraker) |
| i) Publication status   | Votan ,Martyn               |
| j) ENGOT liaison report | Votan per Elser             |
| k) Essential documents  | Shevlin (Powell, Berger)    |

**New Business :**

- |                    |        |
|--------------------|--------|
| a. Trial Budgeting | Martyn |
| b.                 |        |

European Directive updates Votan

AOB

Adjourn

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**Thursday, Nov 6, 2014, 4:00pm – 6:00pm -- Otway 2 Room**

**JOINT: OPERATIONS AND STATISTICIANS**

**AGENDA**

**Welcome and Introduction:** Bryce (MITO) and Nam (KGOG)

**Minuter:**

**New members:**

**Guests:**

**Conflicts of Interest (COI) declarations:**

**Additions to agenda:**

**Approval of minutes – May 2014**

**Website and Harmonization page**

Revisions and updates; trials list; bibliography; roster; etc

**Liaison reports:**

**Exec-BoD**

Bryce/Nam

<b>Ovarian Cancer Committee</b>	Powell/Reuss
<b>Endometrial Cancer Committee</b>	Keller/Reuss
<b>Translational Research Committee</b>	Berger/Hamano
<b>Rare Tumours working group</b>	Votan/Nam
<b>Symptom Benefit working group</b>	Martyn/Gebski
<b>Phase II working group</b>	Blattler/Hamano
<b>CCRN</b>	Martyn/Nam

**Ongoing Business:**

<b>a) QA</b>	Bryce, Farrelly,
<b>b) Harm Manuscripts</b>	Martyn, Votan

**New Business:**

<b>a) Adaptive designs in clinical trials</b>	Farrelly, Hamano
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**GCIG studies**

<b>a. Harmonization IGCS presentations (3)</b>	Martyn, Bryce
<b>b. Lead group issues</b>	

**AOB**

**Adjourn**