



**FINAL**

## **GCIG HARMONIZATION COMMITTEE**

**DoubleTree Hotel, Chicago, IL, USA**

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

**Thursday, June 2, 2016, 4:30pm – 6:00pm – LaSalle II 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: Nov 2015**

### **New Business**

Discussion of morning presentation of PRO\_CTCAE  
Need for creation of Working Group?

### **Ongoing Business**

- a) **Budgeting in Intergroup trials** (Farrelly, Chavez, Berger)
  - Presentation of templates, guidance (Chavez)
  - Presentation of budgeting from previous ENGOT Meeting (Berger)
- b) **Communication in Intergroup trials** (LeFur)
  - Presentation of template
- c) **Intergroup Agreement** (Carty, LeFur)
  - Review of proposal for new wording
- d) **Lead group matrix activity (participation)**
  - Who will take over ?
- e) **Insurance/indemnity** Polleis (Keller, Berger)
  - Update on status of missing Groups

- f) **Group contacts and summaries** Keller (Hiltz)  
Update on status of outstanding Group
- g) **Guidebook** Blattler  
Update/come off agenda
- h) **Mentoring** Nepote (Aotani, Hiltz, Stonebraker)
- i) **Essential documents** Sapetto-Rebow, Berger  
Update
- j) **ENGOT liaison report** Votan for Elser  
European Directive Update
- k) **OTHER New Business**

AOB

Adjourn

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**Friday, June 3, 2016, 3:30pm – 4:30am – LaSalle I 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

Verification by responsible authors that **current** version is available

**Liaison reports:**

<b>Exec-BoD</b>	Stonebraker/Nam
<b>Ovarian Cancer Committee</b>	Carty/Embleton
<b>Endometrial Cancer Committee</b>	Adema/Tu
<b>Cervix Cancer Committee</b>	Hiltz/Reuss
<b>Translational Research Committee</b>	LeFur/Brady
<b>Rare Tumours working group</b>	Votan/Nam
<b>Symptom Benefit working group</b>	Polleis/Gebski
<b>Phase II working group</b>	Blattler/Paul
Discussion regarding logistical and data ownership issues of proposed Umbrella trial	
<b>CCRN</b>	Stonebraker

**Ongoing Business:**

<b>Publication status</b>	Votan, Bryce, LeFur, Carty
<b>Quality Assurance</b>	Bryce/Stonebraker
<b>GCIG studies</b>	
a. Lead group issues	

**New Business:**

**AOB**

**Adjourn**