



FINAL

**HARMONIZATION OPERATIONS COMMITTEE**  
**WEDNESDAY, MAY 29, 2019, 1:30PM – 3:00PM**  
LaSalle I, Hilton DoubleTree Hotel, 300 E. Ohio St., Chicago  
**Chair: Bette Stonebraker Co-Chair: Benedicte Votan**  
**PLEASE SIGN ATTENDANCE FORMS**

**AGENDA**

**Welcome & Introductions:** Stonebraker

**Minuter:**

**New members:**

**Guests:**

**COI disclosures:**

**Additions to agenda:**

**Approval of Minutes/Report: October 2018 (posted on GCIG website)**

**Motion: \_\_\_\_\_ Seconded: \_\_\_\_\_**

**Ongoing Business**

a) **Insurance\Indemnity** Polleis (Keller,Berger)  
Update

b) **Group Contacts and Summaries** Keller(Hiltz)  
Update

c) **Meta-Analysis Working Group Update** Carty, Votan

d) **Mentoring** Stonebraker  
Assignments

e) **ENGOT Liaison Report** Elser (Votan)

f) **Financial Toxicities** Kajimoto

g) **Group discussion regarding topics and assignments. Volunteers solicited and obtained as follows (so far) :**

- (1) Vendor assessment tool – Karen Carty et al (already in progress)
- (2) -Expanding Risk-based monitoring -- Smitha Udagani, Sandra Polleis, Karen Verhoeven
- (3) -Regulatory issues (with CCRN/ Mary McCormack)- Adriana CB, ???

- (4) -Group Audits, Group Evaluation documentation (Vendor Assessment Group?)
- (5) -Other topics/areas

**New Business**

- (h) Best Practices for Patient Advocacy and Clinical Trials –development of Templates (TBN)

**AOB**

**Adjourn**

**HARMONIZATION JOINT OPERATIONS & STATISTICIANS COMMITTEE**  
**THURSDAY, MAY 30, 2019, 3:00PM – 3:30PM**  
LaSalle II, Hilton DoubleTree Hotel, 300 E. Ohio St., Chicago  
**Chair: Bette Stonebraker/Alexander Reuss    Co-Chair: Benedicte Votan /Xavier Paoletti**  
**PLEASE SIGN ATTENDANCE FORMS**

**AGENDA**

**Welcome and Introduction:** Stonebraker/Reuss

**Minuter:**

**New members:**

**Guests:**

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

**Additions to agenda:**

**Approval of Minutes/Report: October 2018 (posted on GCIG website)**

**Motion: \_\_\_\_\_ Second: \_\_\_\_\_**

**Website and Harmonization page:** Smallwood

**Liaison reports:**

**Exec-BoD** Stonebraker/Reuss

**Ovarian Cancer Committee** Levin/Embleton

**Endometrial Cancer Committee**  
**Cervix Cancer Committee**  
**Translational Research Committee**  
**Rare Tumours working group**  
**Symptom Benefit working group**  
**Phase II working group**  
**CCRN**  
**QA Working Group**  
**Meta-Analysis Working Group**  
**Education Working Group**  
**Nominations Working Group**  
**Finance Working Group**

Verhoeven/Tu  
Stonebraker/Reuss  
  
Farrelly  
Polleis/GebSKI  
Paul  
Choi  
Bryce/Votan  
Carty/Paoletti  
Chavez Blanco

**Ongoing Business:**

**Publication status**

- a. Abstract to IGCS

Kajimoto

**GCIG studies**

- a. Lead group issues

**New Business:**

**AOB**

**Adjourn**