



FINAL

HARMONIZATION OPERATIONS COMMITTEE  
WEDNESDAY, OCTOBER 17, 2018, 4:00PM – 5:30PM  
SEMINAR ROOM I, KLINIKUM DER UNIVERSITÄT MÜNCHEN, DEPARTMENT OF GYNECOLOGY AND  
OBSTETRICS, CAMPUS INNENSTADT, MAISTR. 11, MÜNCHEN

CHAIR: B. STONEBRAKER CO-CHAIR: B. VOTAN

*PLEASE SIGN ATTENDANCE FORMS*

### AGENDA

Welcome & Introductions: Stonebraker

Minuter:

New members:

Guests:

Conflicts of Interest (COI) declarations:

Additions to agenda:

Approval of Minutes/Report: May 2018 (posted on GCI website)

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

### Ongoing Business

- |   |                         |
|---|-------------------------|
| a) Budgeting<br>Update                    | Chavez                  |
| b) Insurance\Indemnity<br>Update          | Polleis (Keller/Berger) |
| c) Group Contacts and Summaries<br>Update | Keller (Hiltz)          |
| d) Meta-Analysis Working Group Update     | Carty, Votan            |
| e) Mentoring<br>Assignments               | Stonebraker             |
| f) ENGOT Liaison Report                   | Elser (Votan)           |
| g) Financial Toxicities                   | Kajimoto (Bryce)        |

## **New Business**

### **h) QA**

All

Group Discussion regarding topics and assignments

Suggested topics:

- i. Vendor assessment tool
- ii. Expanding Risk-based Monitoring documents
- iii. Regulatory Issues (with CCRN)
- iv. Group Audits, Group Evaluation documentation
- v. Other topics\areas

## **AOB**

**Adjourn**

HARMONIZATION JOINT OPERATIONS & STATISTICIANS COMMITTEE  
THURSDAY, OCTOBER 18, 2018, 4:00PM – 4:30PM  
SEMINAR ROOM I, KLINIKUM DER UNIVERSITAT MUENCHEN, DEPARTMENT OF GYNECOLOGY AND  
OBSTETRICS, CAMPUS INNENSTATDT, MAISTR. 11, MUNCHEN  
CHAIR: STONEBRAKER/REUSS CO-CHAIR: VOTAN /PAOLETTI

*PLEASE SIGN ATTENDANCE FORMS*

AGENDA

Welcome and Introduction: Stonebraker/Reuss

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

Website and Harmonization page: Smallwood

New Business:

Common Data Elements Reuss/Stats  
Identification and standardization of key variables

Liaison reports:

Exec-BoD Stonebraker/Reuss  
Ovarian Cancer Committee Levin/Embleton  
Endometrial Cancer Committee Verhoeven/Tu  
Cervix Cancer Committee Stonebraker/Reuss  
Translational Research Committee  
Rare Tumours working group Farrelly  
Symptom Benefit working group Polleis/Gebski  
Phase II working group Blattler/Paul  
CCRN Choi  
Meta-Analysis Working Group Carty/Paoletti  
Education Working Group Chavez

**Ongoing Business:**

**Publication status**

Bryce

**GCIG studies**

- a. Lead group issues**

**AOB**

**Adjourn**