



GCIG-HARMONIZATION COMMITTEE

May 31, 2012

Doubletree Magnificent Mile Hotel, 300 East Ohio Street Chicago, IL

MINUTES

Present:

Members:

ACRIN:	absent
AGO-Au:	+
AGO-OVAR:	S. Polleis, A.Reuss
ANZGOG:	J.Martyn, V.Gebiski
COGi:	A.Buchin
DGOG:	
EORTC:	A.Negrouk
GEICO:	F.Nepote
GICOM:	
GINECO:	N.Le Fur, B.Votan
GOG:	M.Brady, B.Stonebraker
GOTIC:	E.Aotani
ICORG:	A.Shevlin
JGOG:	E. Aotani, +
KGOG:	E-K.Park, J-S.Kim, BHNam
MaNGO:	
MITO:	J.Bryce
MRC/NCRI:	L.James
NCIC-CTG:	A.Hiltz, D.Tu
NSGO:	G. Anderson
SGCTG:	J.Paul, K Carty
GCIG:	M.Bacon

OPERATIONS /DATA MANAGEMENT AND STATS

1. Welcome and Introduction:

Monica Bacon introduced Jane Bryce as the new Chair who welcomed and introduced participants. Julie Martyn, outgoing Chair, will mentor Jane and Jane will mentor Bette Stonebraker, incoming Co-chair. Monica Bacon (MB) introduced the Declaration of Conflict of Interest as the first order of business in

our meetings. No participants declared any conflict of interest. Jim Paul was introduced as the incoming Chair of the Harmonization Statisticians Group.

2. Approval of minutes

Minutes of meeting September 8, 2011 (Milan) will be corrected to reflect that Eriko Aotani of JGOG was in attendance. The corrected Minutes were unanimously approved (Motion by Julie Martyn (JM) seconded by Mark Brady (MFB)).

3. Minuter: Bette Stonebraker (BS) minuter for this meeting

4. Website Issues and Updates

- a. Michelle Powers has left the role of GCIG Webmaster and MB introduced our new Webmaster, Sonja Easley.
- b. It is noted that the GCIG Website is out of data and Sonja will begin to update.
- c. Discussion took place regarding a having a password protected area for the purpose of posting slides or documents for limited viewing.
- d. Sonja will be meeting with Michael Bookman, IGCS webmaster, for advice and assistance.
- e. Suggestion was made to consider providing access to the Guidebook and templates via the web.
- f. Sonja will work with Members to update contacts and roster information.
- g. All Harmonization Members are asked to cruise and critique the Website and provide feedback to Sonja.

5. On-going business

- a. **Group contacts and summaries:** JM is continuing work on this. Groups are again asked to review, update and send changes to Julie. Discussion took place how to best make use of this document and posting as a Web application is being considered. MB explained to new members the purpose of the Group Contact and Summaries and The Guide Book, including the importance of keeping the documents up-to-date.
- b. **Guide Book:** It was felt that the Research Agreement template needs updating. A subcommittee was formed to assist Karen Carty. Anastasia Negrouk (EORTC) and GINECO members, Nathalie Le Fur and Brigit Voltan will join this subcommittee. Other interested members should contact Karen. Issues of "sponsorship" and template vs. guidelines will be addressed.
- c. **Translational research and tumor banking:** Natalie will update us at the next meeting. It is noted that the Checklist is available in the Guidebook and is an on-going document.
- d. **Nursing studies (aka Non-treatment trials)& potential:**
 - i. OV-21 (MB) Nursing complications -on-going
 - ii. Symptom Benefit (JM) recruiting (57/800 pts.) collecting baseline, FU, pt. reported outcomes.

- iii. MITO-12 (JB) –ongoing collecting sentinel events, describing symptoms as predictors of ov ca; describe time interval of sentinel events.
- e. **QoL instruments** (KW)discussion of tools used
 - i. EORTC, FACT, FACTO, FACIT – multiple languages
 - ii. GEICO- FOSI subset of FACT
 - iii. FACIT available in English, French, Spanish, Japanese, Korean
 - iv. Defer to Stats for future discussion
 - v. Symptom Benefits Group may be putting together list of Instruments.
 - vi. Val Gebski-meta analysis: 3 trials, same QOL instruments, too many instruments, too many time points
 - vii. Library of Instruments
 - viii. EQ5D questionnaire, cost utility
 - ix. Prospective reminders available: RTOG Vision Tree
 - x.
 - f. **Mentoring –Monica**
 - i. Year- long Observation status Group to Group, MD and Stats
 - ii. Frederico to mentor Mexican Group
 - iii. Anna (Ireland) to be mentored by MRC

6. New Business

- a. Parallel Surveying – Monica
- b. Friedlander survey –funding levels- all over the board
- c. Quinn –Quality Assurance- out of Strategic Planning
 - i. Protocol violations all across the board
 - ii. Monitoring all across the board
 - iii. Small subcommittee of Executive Board to add to minimum criteria
 - iv. Lederman to revisit governance documents -2 volunteers from Operations needed

7. GCIG Studies

- a. SHAPE- looking to activate by July

8. Future Meeting agenda item

- a. Approaches to collecting data on International trials

9. Next meeting: to be held in Leiden, December 1 and 2, 2012

Meeting adjourned.

Respectfully submitted,
Bette Stonebraker