GYNECOLOGIC CANCER INTERGROUP (GCIG)

HARMONIZATION COMMITTEE

THURSDAY, OCTOBER 21, 2010, 3:30 P.M. , PRAGUE, CZECH REPUBLIC

MINUTES

Present:

Members:

AGO-Au:	M.Hardiman
AGO-de:	S.Polleis, A. Reuss
ANZGOG:	J.Martyn
COGI:	J.Berek
DGOG:	K.Adema
GEICO:	F.Nepote
GINECO:	N.leFur,
GOG:	M.Brady, B.Stonebraker
ICORG:	D.O'Donnell
JGOG:	E.Aotani
KGOG:	EK.Park, SH. Kim
MaNGO:	R.Fossati
MITO:	J.Bryce
MRC/NCRI:	L.Farrelly, W.Qian
NCIC CTG:	M.Bacon, D.Tu
NSGO:	G.Andersen
SGCTG:	K.Carty, J.Paul
Ex-Officio:	M.Powers

Pharma/Biotech Partners:

Ortho Biotech:	D.Atlan

1. **Welcome and Introduction:**
   J. Martyn (JM) opened the meeting, welcomed and introduced participants

2. **Approval of minutes**
   Minutes of meeting June 3, 2010 (Chicago) unanimously approved

3. **Minuter:** J. Bryce

4. **Additions to agenda:**
   the following additions were proposed:
   a. Screening logs (JB) see operations "New Business"
   b. Italian project of collating information re: complications related to gynaecologic surgery (M Bacon - MB)

5. **Trial Updates /Bibliographies reminder**
   M. Powers (MP) received updates on all trials. Some reminders:
   a. If additional information needed members will be queries;

b. Please confirm email addresses;
c. Lead group only should post the GCIG trial main info and associated publications;
d. When posting trials on GCIG, include Eudract number when present and/or the trial registry number

Regarding publications/bibliography

e. Bibliography on website needs updated (incongruent with pubmed search for GCIG published studies);
f. For retrospective pubs, MP will email list of info to include
g. GCIG guidelines for pubs and how to manage
h. Specific queries to MP

6. Ongoing business

a. **Group contacts and summaries**: Group contact and summaries list has been circulated (K. Carty, S. De Polleis). If not received contact Michele by Nov 30.
b. **Translations research:** review checklist consent forms new as appendix to guidebook. No pending actions. Send any feedback to J. Martyn
c. Informing participants of study results: MRC provided examples from OV-05 and ICON 7 (see attached, again Michele has these?) Information is for patients, and this is a model for discussing results, not a mandatory form to give pts. The text can be modified (as similarly done with informed consent changes to meet various groups' needs). Also available examples translated byAGO, ANZGOG, NGOG.
d. Nursing studies & potential:
    i. OV-21 (MB) recruiting
    ii. MITO-12 (JB) recruiting
    iii. VENUS (JM) discussing in symptom benefit study
    iv. MB proposed collaboration for a publishing an education program (core competencies) for Research Nurses with particular focus on conduction of international, intergroup trials.
    v. JM clarified that nurses may be Pis in the ANZGOG Symptom Benefit Study

e. QoL instruments: not discussed
f. **Remote Data Capture archiving:** J. Paul responses on 8 groups. Email will be recirculated for missing responses. Completed survey to be attached to minutes. Thus far, there is a mix between home-made systems (MITO; GINECO, ANZGOG), purchased applications (macro AGO, MRC), with a trend of moving towards commercial systems - medidata RAVE system (NCIC, JGOG, some US). Important to have info regarding infrastructures to seek/ensure compatibility.
g. Secure emails and digital protection of sensitive data: no updates on this, survey to be sent to members regarding website and email protection procedures in use
h. Updates on CDEs: MB gave a brief description of the what and M Brady on the why of common data elements. CDEs will be distributed with links. Please review base data collection / CDEs and bring questions. So far, not mandatory (except NCI-USA studies) but GCIG will try to follow. Each group has autonomy re: CDE. Brian Campbell (Emmes/NCI) has offered to review our forms for CDE compliance and mapping to
i. Updates on CTCAEv4: newer versions (e.g. 4.0.3) have been released, but possibility of rolling (continuous updating of) criteria on active protocols less likely. Important to clearly reference both version number and date within the study protocol.

7. New business:
    a. **Spreadsheet of all GCIG clinical trials** has been created. If need access request to MP
    b. **EORTC conventions list** (MB): this is helpful tool to close the query process where sponsor declares it will not query a particular data entry any more if…(and list of conventions are inserted, e.g. self-evident, etc). MB requesting permission from EORTC to distribute this convention with minutes.
    c. Action letter for carboplatin: MB reviewed recent action letter regarding AUC based dosing of carboplatin, released by NIH Oct 1, 2010. Since meeting a follow up letter dated Oct 22, 2010 was released. **Please review** both letters, attached (still need Oct 1 letter). In US all laboratories will have switched to the IDMS method for the measurement of serum creatinine by Dec 31, 2010. Importantly, Sponsors must VERIFY that the treatment plan does NOT contain a correction factor used to calculate carboplatin doses based on IDMS serum creatinine. This is mandatory for all NCI trials.
    d. **Discussion of unit values on CRFs**: MB lead groups should provide selection for unit of measurement for certain lab values (e.g. haemoglobin) where variance is known to exist. Then the Central Data Center of the sponsor is responsible for conversions**.** Further discussion on this will be held at next meeting
8. **GCIG support of Harmonization and Operations group**: MB: By statute, each GCIG member group must have a representative at the Harmonization and Operations Committee meeting. The GCIG Executive Board will consider requests for up to 1000 CAD reimbursement for travel expenses to Harm/OP Committee members for attendance at the next meeting in Chicago, upon specific request.

9. **Next meeting:** to be held in Chicago, June 2-3 2011.

Operations/Data management issues:

1. Ongoing Business

- Group Specific Apppendix template (minimum requirements) L. Farrelly email out and feedback (ICON-6 generalized). Study Appendix vs Study Guide Handbook (in order to avoid amendments for general logisitics such as address changes, faxing, drug supply issues, SAE reporting and other such variances per country. To be inserted in main protocol a statement such as “See country specific appendix” Next meeting agenda item for handbook.

- Survey of policies/processes- Queries / Deficiencies / Monitoring and Protocol Deviations/violations JB and MB will work on revising this survey Jan/Feb for sendout before spring meeting

- EU Directive updates : general discussion on trial registries, required (Eudract number for Member States) and public registries (clinical ìtrials.gov). Please include these in trial updates (website, bibliography).

2. New Business

- Should screening logs be mandatory in GCIG trials? Currently used as recruitment tool, kept at site and not mandatory for submission with other regulatory documents.

- ENGOT updates

Next meeting: Chicago June 2,3, 2011. See website for updates

Meeting adjourned.
Respectfully submitted,