



GYNECOLOGIC CANCER INTERGROUP (GCIG)

HARMONIZATION COMMITTEE

JUNE 2, 2011 2.00 – 4.00 PM HILTON HOTEL, CHICAGO

MINUTES

Present:

Members:

AGO-de:	S.Polleis, A.Reuss
ANZGOG:	J.Martyn, V.Gebiski
COGI:	A.Buchin
DGOG:	K.Adema
EORTC-GCG:	A.Negrout
GEICO:	F.Nepote
GCIG:	M.Bacon
GICOM:	J.Hurtado
GINECO:	N.Le Fur, B.Votan
GOG:	M.Brady, B.Stonebraker
ICORG:	B.Mouton
JGOG:	E.Aotani
KGOG:	B-H.Nam
MaNGO:	R.Fossati
MITO:	J.Bryce,
MRC/NCRI:	W.Qian
NCIC CTG:	A.Hiltz, D.Tu
NSGO:	G.Andersen
RTOG:	K.Winter
SGCTG:	K.Carty,
Ex-Officio:	M.Powers

1. Welcome and Introduction:

J. Martyn (JM) opened the meeting, welcomed and introduced participants

2. Approval of minutes

Minutes of meeting 21 Oct, 2010 (Prague) unanimously approved

3. Minuter: J. Bryce

4. Trial Updates /Bibliographies reminder

M. Powers (MP) bibliography updated by the trial lead groups. Copyright issues still to be addressed. The GCIG roster information will be query. Each group should have ONE (nondigital) postal address for mailings and ONE central fax. Each group would then be responsible for distributing material within its groups.

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5. Ongoing business

- a. **Group contacts and summaries:** Proposed to change the format so that information is presented comprehensively by group, rather than by topic. Please review information that MP has emailed to verify information to be included. Send responses to JM by June 30.
- b. **Translations research and tumor banking:** translational research and tumor banking were discussed together
 - i. **Translation research** checklist for translational research is part of guidebook and will include what is required for inclusion in the translational research consent form
 - ii. **Tumor banking** survey was distributed end of May by email. Group discussion regarding SOP and quality control processes in place regarding the actual analyses (assays), as well as data entry, particularly since some tissue banks are “virtual” (data shared rather than tissue samples actually being sent). When specimens are sent, a sort of tissue “tracking” should be available. Consent and procedural issues also discussed. NLF will redistribute questionnaire to groups. Please respond as soon as possible.
- c. **Nursing studies & potential:**
 - i. OV-21 (MB) recruiting
 - ii. Sexual health substudy (endometrial) is being published
 - iii. MITO-12 (JB) recruiting MITO, MANGO. GINECO to start.
 - iv. JM ANZGOG SB recruiting and trial meeting later today
- d. **QoL instruments** Kathryn sending survey re: tools in use. SB has 4 foci: survival, elderly, PROs, and one additional area of focus to be advised and distributed at a later date. Survey to avoid overlap of questionnaires and look for synergy if possible.
- e. **Remote Data Capture archiving:** J. Paul will recirculate questionnaire...data lost due to equipment theft! Please respond as soon as possible after receiving the questionnaire.
- f. **Updates on CDEs:** No further news on CDEs. MB reviewed again for group that Common Data Elements are mandatory in US led studies. CDE not required for GCIG studies, but groups will try to use same variables if not same wording. Reminder to group that each group has autonomy re: CDE, and that Brian Campbell (Emmes/NCI) has offered to review our forms for CDE compliance and mapping.
- g. **Updates on CTCAEv4:** most new studies are using this version of CTCAE. US ongoing trials are converting to version 4. Not a requirement to convert ongoing GCIG trials.
- h. **Travel support** MB clarified that the Executive committee has committed to supporting 1 person per group per year with a travel grant of max 1000 CAD . Ten (10) harmonization committee members applied for the grant for this meeting.

6. Open discussion:

Issues related to the collection and analysis of protocol violations was discussed. Group collection practices, definition of major PV, and general practices of including or excluding patients who do not meet eligibility criteria or who deviate from protocol were discussed. The statisticians point of view (in general) is that in the primary analysis, which is based on intention to treat, no exclusions are permitted (and are not necessary either as ITT runs against null hypothesis). In sensitivity analyses per protocol, patients may be excluded, for example if never having received agent. In any case, exclusion of subjects in such analyses should be clearly stated in the publication. Some groups do have policy clearly stated (RTOG includes only eligible patients in their analyses) and some groups clearly define protocol violations within the protocol (KGOG), though most groups do have a review process at end of trial. Further discussion was opted to Operations meeting

7. GCIG studies (lead group issues only)

ANZGOG: SB 1st international group on board (ICOG – Ireland); OUTBACK: GOG will join.

MITO: MITO 7: MANGO in, GINECO and HeCOG joining. MITO 8: AGO and BGOG in; MITO 12 (see above nursing studies)

AGO: OVAR -16 closed, OVAR-12 1198/1300 anticipate accrual completion end of June; LION 474 / 640 ; DESKTOP 3 19 pts, GINECO and Shanghai GOG joining.

SCOTROC-4 , to be published

DGOG Portec 3 amendment pending

Mexico

NCRI Meal trial 8/300 NSGO, MANGO, MITO DGOG, GINECO to participant; submitting neoadjuvant dose dense study for cervix

MRC ICON-6 220 pts, ICON-7 paper being published, ICON 8 opened

RTOG 0724, post operative pts..18 pts enrolled, amended inclusion criteria and accrual extended by 1 year..OPEN to all

GOG 240 Geico added. Problem with company supplying bevacizumab outside of US ; 218 being published.

JGOG 3017 reached accrual 667 pts, opene IP trial with 19 pts enrolled

GINECO accrual reached Aurelia.

MANGO Innovation to start with 150 sites in Europe, substudy in AGO OVAR-12 on biomarkers

NCIC OV-21 activated 2 sites in UK, SHAPE surgical study for early stage cervix..90 pts Canada, 13 groups declared interest

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

Operations/Data management issues:

1. Ongoing Business.

- Survey of policies/processes- Queries / Deficiencies / Monitoring and Protocol Deviations/violations MB and JB presented previous survey questions and responses to discuss with group what are the key issues that should be addressed / harmonized / and or described by GCIG member groups. In general, group agreed that survey should continue with the goal of educating member groups for the prevention and reduction of protocol deviations. Some discussion on education measures was held (newsletters, tools, etc). The forthcoming revised survey will include issues regarding education to sites (available) and processes for evaluation of PVs a priori and post trial, as well as consequences. JB and Andrea will develop new survey to be emailed to operations committee members.
- EU Directive updates none

- Group specific appendix format being modified
- ENGOT updates the roadmap is being developed and delineates tasks of lead group. Road map, when completed, will be published by ENGOT.
- AGO GCP teaching modules. SP presented the AGO model of showing satisfactory evidence of GCP education for its group, as part of mandatory education available at regular AGO meetings.
- MB reminded us to document clearly if patient comes off treatment for toxicity, versus off treatment for withdrawal of consent.

Next meeting: Milano, September 8, 9 2011. See website for updates

Meeting adjourned.

Respectfully submitted,