GYNAECOLOGIC CANCER INTERGROUP (GCIG)
Harmonization Working Group

June 06th, 2006, Atlanta

MINUTES

	PRESENT:	ABSENT:
EORTC:		U. Bethe, C. Coens
NCIC CTG:	M. Bacon, E. Eisenhauer	
AGO:		C. Shade-Brittinger
SGCTG:	K. Carty, J. Paul	
GOG:	B. Stonebraker, M. Brady	
NSGO:	G. Andersen, R. DePont	
MRC:	C. Amos, AM. Swart, M. Parmar,	
ANZGOG:	J. Martyn	
RTOG:		K. Winter, D. Grant
GINECO:	B. Votan, N. LeFur	
GEICO:		A. Gonzalez
GOG-J:	E. Aotani	Kigawa
NCI US:		
MaNGO	R. Fossati	
MITO:	S. Pignata	
AGO Austria:		J. Ulmer
Website:		Mason Schoenfeldt

1. Welcome and Introductions C. Amos, M. Bacon.

2. Minutes, November 3, 2005 – no corrections
Motion: J. Paul; second: M.Bacon; approved – all
Volunteer minute-taker: K.Carty

3. Group Contacts and Summaries
C. Amos on behalf of G.Elser
Claire gave an overview on the group contact and summaries list. Mango representative has to provide their groups details to Gabriele.
Monica highlighted how helpful the group contacts and summaries are in developing intergroup trials for e.g. CRFs it is useful to know requirements of the different groups.
This document is available on the GCIG website.
Action Points:

- Claire to check with Mason that the current version of the document is on the website and confirm to group members when this is the case
- Groups should check details are correct when current version is on the website
- Mango Group to send group details to Gabriele

4. Translational Research
J. Martyn
The ANZOG group have taken the lead in moving this project forward. Documents were circulated prior to the meeting summarizing the discussions, which took place at the November meeting in Paris.

It has been decided a checklist is to be developed for the use of GCIG groups for the development of tissue consent forms. Working party to be formed to work on this, suggested representative from NCIC, MRC and EORTC groups will work with ANZGOG on this. The checklist will summarize the basic principles required in tissue consent forms and act as a template for guidance to form trial specific documents. Harmonization group will work closely with the translational group on this project.

Checklist will be put together by ANZGOG within 1 month, following this a teleconference will be organized with working party to discuss. The checklist will be finalized prior to the next meeting to take to the translational group.

Groups were previously asked to send sample template forms from their group to ANZGOG. Any groups which have not already sent a template please do so.

Action Points:

- ANZGOG to put together checklist within next month and organize teleconference with working party
- Subsequently agreement to be circulated to group for final agreement/comment

- Final agreement to be submitted to translational group for discussion at their next meeting
- Please send any outstanding template forms to ANZGOG.

5. Education /Guidebook

Update given by Rene De Pont.

Elisabeth Eisenhauer had commented on the guidebook, one of the concerns was whether or not an Independent Data Monitoring Committee should be required on every trial. General consensus was that it is not required for every trial but it is a requirement for large randomized trials.

To look at various organizations (FDA, WHO, MRC) guidance on Data Monitoring Committees and draft appendix for guidebook – Jim Paul has agreed to do this.

Action Point:

- Jim Paul to do Data Monitoring Committee appendix for guidebook.

6. Intergroup Agreement

Ann Marie Swart reported back the MRC have used the inter group agreement for ICON 7 they have found it very useful.

- An updated version of the agreement will be circulated.
- Ann Marie commented that it not possible to delegate sponsor responsibilities but can delegate sponsor activities.
- It maybe the agreement will require to be adapted country per country depending on requirements of each country.
- The agreement will change over time as different groups use the document.

The EORTC are also using the agreement for their current Tarceva study and GINECO have used it in Calypso.

7. Neurotoxicity Coding

Jim Paul summarized review of neurotoxicity scale. Scales developed by the SGCTG, EORTC, AGO and GOG had been examined. The review recommendation was that the GOG toxicity questionnaire NTX-4 should be adopted for GCIG studies once the validation paper had been accepted for publication. Mark Brady informed the group that this paper has been written and recently submitted to Annals of oncology. Mark will be happy to circulate a copy of the paper to allow group members to assess the questionnaire and its properties.

Monica raised the importance of monitoring neurotoxicity levels during follow-up in light of a recent BMC paper (Residual neurotoxicity in ovarian cancer patients in clinical remission after first-line chemotherapy with carboplatin and paclitaxel: The Multicenter Italian Trial in Ovarian cancer (MITO-4) retrospective study, Pignata S et al http://www.biomedcentral.com/content/pdf/1471-2407-6-5.pdf). Mark commented that repeated use of NTX-4 during follow-up would meet this need, but compliance may be a problem.

8. CTCAE Version 3

Following the recent alert on IP therapy in ovarian cancer there was discussion about the possibility of adding IP specific toxicity list to CTCAE version 3. It is felt that it will be unlikely that an update will be required as all the IP toxicities appear to map to existing terms.

Bette Stonebraker circulated to the group a list of terms from CTCAE version 3 which could be used for IP toxicities.

9. Common Data Elements (CDEs)

CDEs, which are the standardized terms for the collection and exchange of data were discussed. All groups should follow CDEs when developing CRFs for studies.

It is felt that there is big gap in surgical CDEs, groups to let Claire know of any terms which they think should be added.

10. GCIG Specific Study issues

Brief updates given on GCIG trials by each group:

- EORTC 55971 there should be enough patients for the study by end of December.
- EORTC Tarceva trial – EORTC have approx 40 patients. GINECO + AGO now on board. There are mandatory specimen collections in the study. The study requires 1200-1400 patients.
- NCII CTG OV16 (Cisplatin Topotecan vs Carboplatin Taxol) completed accrual last June. Will have progression data by fall. Lot of overdue data for the study. First results will be presented next year.
- CALYPSO (GINECO) – 270 patients, end of recruitment expected Oct 07. TSC met the previous day. Problems with collection of QoL.
- ICON 6 (MRC) Second line trial looking at VEGF Inhibitor. Draft protocol has been circulated to GCIG groups. Planning to open December 2006 in limited number of centers in UK + Canada. Comments required by 26th June 2006.

  In the context of this study the issue of whether or not pfs was an acceptable end-point in 2nd line studies was raised. It was not clear that a difference in pfs actually translates into a real clinical benefit in

terms of either QoL or survival. The issue of the relationship between pfs difference and survival difference was an issue that could be addressed by the statistical group and each group should look at its second-line trials to see what data is available.

- ICON7 (MRC) now have final protocol. Due to open Sept / Oct 2006.
- JGOG Clear Cell Carcinoma Study – Had logistic meeting during ASCO. Following suggestions the protocol will be revised and distributed in approx 2 weeks.
- ASTEC (MRC) Endometrial trial, mid 2007 for analysis.
- SCOTROC 4 (SGCTG) ANZGOG participating in study. Currently 393 patients recruited. Study is compatible with MRC CHORUS study.
- The Italian MITO Group have a study in first line ovarian cancer of Carbo/ Taxol vs Carbo/ Caelyx, 500 patients have been recruited. 7 centers in Italy and 1 in Portugal. The target is 820 patients.

11. Future Directions:

Elisabeth Eisenhauer made the case that we should work to make sure that recent developments do not become future barriers to collaboration. Items that could fall under this heading are:

– Electronic data capture: Open communication with other groups regarding this.
- Increasing regulatory requirement for SAE reporting which differs between countries make it vital to develop viable models for SAE flow.

Next meeting

- October 2006 Santa Monica IGCS
- June 2007 Chicago ASCO

13. Meeting Adjourned

Respectfully submitted,

Karen Carty and Jim Paul