GYNAECOLOGIC CANCER INTERGROUP (GCIG)
Harmonization Working Group

May 29th, 2008, Chicago

MINUTES

	PRESENT:	ABSENT:
EORTC:		
NCIC CTG:	M Bacon	E Eisenhauer
AGO:	G Elser, A Reuss	
SGCTG:	K Carty, J Paul	
GOG:	M Brady, B Stonebraker	
NSGO:	G Andersen, R De Pont	
MRC:	H Kitchener	J Bakobaki, W Qian
ANZGOG:	A Boland, V Gebski	J Martyn
RTOG:	K Winter	
GINECO:	N LeFur, B Votan	
GEICO:		
GOG-J:	E Aotani	
NCI US:		
MaNGO:		R Fossati
MITO:		S Pignata
AGO Austria:		J Ulmer
SWOG:	G Anderson	
Website:	M Schoenfeldt	

Observers: K Morinaga (Taiho Pharmaceutical)

1. Welcome and Introductions G Elser, M Bacon

2. Minutes, October 18,2006 – no corrections
Motion: K .Carty; second: B Stonebraker; approved – all
Volunteer minute-taker: K.Carty

3. Group Contacts and Summaries
Brief reminder of purpose of the document was given. It was highlighted how helpful the group contacts and summaries are in developing intergroup trials. It is important that document is kept up to date, any changes to individual groups should be sent to Gabriele. Some details are outstanding for document from MANGO and ACRIN.
Rene De Pont informed group he is leaving NSGO.
Action Point:
- Groups should check details are correct and update Gabriele accordingly of any changes.

4. Intergroup Agreement
The intergroup agreement is being used by most groups all agreed it is proving useful. Agreement is currently being used for both ICON 6 and ICON 7 studies with no problems. The agreement will be also used for JGOG Clear Cell Carcinoma study (between JGOG and SGCTG) and for new endometrial study being run by Dutch group, which NCIC will collaborate with Dutch group on.
The agreement will change over time as different groups use the document. Groups should provide updates/feedback at harmonization group meetings to enable the template to be updated. MRC are owners of the document.

5. Translational Research
The translational research checklist, which was developed by the harmonization group for use in GCIG trials has now been approved by the translational group. It was agreed it would be useful to pilot the checklist in future studies. It is planned the checklist will be used in following 2 studies PORTEC 3 and JGOG Clear Cell Carcinoma study, feedback on this will be provided at future meetings.

6. Education /Guidebook
Update given by Rene and an overview on purpose of guidebook. The guidebook is an educational tool for groups to see how other GCIG groups conduct trials. Rene has kindly offered to finish the work he is doing on the guidebook.

Prior to the meeting Jim Paul circulated the updated Data Monitoring Committee (DMC) section of the appendix. This section sets out a framework of minimum requirements for DMC's for GCIG trials. There was further discussion regarding some of the points within the document, particularly 5th bullet point. General consensus from all was the document should be considered as a guideline covering the key points in relation to DMC's. New version of the document has to be taken to Executive Board for approval.
Action Point:

- New version of DMC section of guidebook to be taken to Executive Board for approval.

7. GCIG Website
Mason provided an update on GCIG website which is being migrated to IGCS website. In the interim until the migration between the websites is complete, anyone requiring a document from downloads section of the GCIG website should email Mason who will forward the documents on.

8. Monitoring Issues
Prior to the meeting a survey on monitoring issues was sent out to each group. The aim of the survey is to find out what the minimum expected level of monitoring is for each group. The information collected from each group will, be helpful to groups to budget and plan for the respective groups participating in Intergroup trials. It will also indentify any factors that would prevent a group from participating in a trial. Further discussion and clarification on some of points on survey – it was suggested it would be helpful to have an introductory page explaining each point. From discussions had it would seem the majority of groups do a similar % of source data verification.
9. eRDC Update

Following on from discussions at previous meetings on experiences of group's in relation to commercial solutions and requirement specifications in relation to electronic data capture an update was given by each group to what stage they are at in relation to electronic data capture. From updates given it was clear there are only a few groups who are using electronic data capture for all their trials. It was agreed by all it would helpful to keep this as an agenda item for future meetings.

10. GCIG Specific Study issues

Brief updates given on GCIG trials:

- AGO (DESKTOP–II) (Evaluation of predictive factors for complete resection in platinum sensitive relapse) – Study will be presented at Bangkok.
- AGO (LION) (Lymphadenectomy in ovarian neoplasm) – target 640 pts.
- NCIC have a proposed ovary intraperitonal study
- ICON 7 (MRC)(1st line Avastin) – study moving on, accrual slower than expected.
- ICON 6 (MRC)(2ND line AZD2171)- stage 1 of study (safety period) will be in selected centers in UK and Canada.
- CHORUS(MRC) – Update will be given at general assembly.
- JGOG Clear Cell Carcinoma –study currently recruiting in Japan and Korea (SGCTG, GINECO and MITO also plan to participate in trial. 192 patients currently recruited. First IDMC will take place on 01/JUN/2008.
- CALYPSO (GINECO) – safety data will be presented as poster presentation at ASCO.
- SCOTROC 4 (SGCTG) (1st line Carboplatin) ANZGOG participating in study. Currently 849 patients recruited.
- SGCTG have study in pipeline of weekly carbo/taxol vs caelyx in 2nd line ovary.
- GOG 218 Avastin trial is still recruiting.
- GOG have mucinous trial which is being done in parallel with MEOC-1 trial in the UK.
- RTOG cervix study will be discussed at general assembly.
- EORTC Tarceva trial closed to recruitment in February.
- EORTC 55971 Neoadjuvant trial – analysis will be done summer, with results in fall. Results of this study will be important
- NSGO no new studies at moment.
- SWOG updated currently developing a phase II protocol.
- ANZGOG updated currently doing following trials:
    - Phase II IP trial
    - Symptom benefit trial
    - 2 surgical trials
    - LACE (Laparoscopic surgery vs Abdominal surgery) study jointly run through MD Anderson and Brisbane

11. Any other Business

- It is requirement for each GCIG working group to have a Co-chair, Benedicte Votan has kindly agreed to taken on this role for the Harmonization group.
- Mark Brady will be the successor of Rene du Point in the statistician group.

- Monica updated the new version of the Manual for Clinical Trials Nursing has recently been published. Many of members of the GCIG harmonization group have contributed to the international chapter of the manual. It was agreed this is a good example of harmonization working well.

12. Future Directions:

- Update given about ENGOT – which is a European organisation which has been set up to increase collaboration in European gynae trials. The group is particularly looking at complications of EU Directive. Group has been set up by Ignace Vergote.
- Monica informed of a 2 day initiative which recently took place in Washington, with various groups looking at improving international collaboration. Monica found out details of this from Dr Ted Trimble. A working group was formed at the meeting similar to operations/harmonization group of GCIG but not specific to disease sites. Monica has forwarded GCIG harmonization documents to participants of the meeting, it was felt the documents would be a useful resource for parallel efforts towards international collaboration as oppose to another group duplicating work which has already been done by GCIG.

<u>Part II. Operations Group</u>

- Benedicte Votan from GINECO gave feedback from a competent authority (CA) inspection, which took place in October/November 07 at GINECO. 2 studies were inspected (ICON 7 + a national study). The presentation was very informative on what to expect when selected for inspection. Benedicte's presentation will be available on the website.

- The operations group, have previously prepared a document summarizing the essential documents required by all groups, this document is now complete.

- Discussion took place on safety reporting requirements in each country.

- There was a brief discussion about the differences in groups in relation to using protocol signature forms, site acceptance forms, membership contracts, trust agreements – board agreements etc. Also discussed how each group selects sites/Investigators to participate in their trials. It was agreed these points should be discussed in further depth at the fall meeting.

Next meeting

- November 14 -15 2008, Liverpool

Meeting Adjourned

Respectfully submitted,

Karen Carty