GYNAECOLOGIC CANCER INTERGROUP (GCIG)
Harmonization Working Group

June 04th, 2007, Chicago

MINUTES

PRESENT:

	PRESENT:	ABSENT:
EORTC:		C Coens, U Bethe
NCIC CTG:	M Bacon, E Eisenhauer	
AGO:	G Elser, A Reuss	
SGCTG:	K Carty, J Paul	
GOG:	M Brady, B Monk, B Stonebraker	
NSGO:	G Andersen, R De Pont	
MRC:	C Amos, J Bakobaki, W Qian	
ANZGOG:	C Brown, V Gebski	J Martyn
RTOG:	K Winter	D Grant
GINECO:	N LeFur, B Votan	
GEICO:		A Gonzalez
GOG-J:	E Aotani	Kigawa
NCI US:		
MaNGO:		R Fossati
MITO:		S Pignata
AGO Austria:		J Ulmer
Website:	M Schoenfeldt	
Observers:	K Morznaga (Taiho Pharmaceutical) Dr Kim (Korea)	

1. Welcome and Introductions C Amos, M Bacon

2. Minutes, October 18,2006 – no corrections
Motion: M. Bacon; second: J. Paul; approved – all
Volunteer minute-taker: K. Carty

3. Group Contacts and Summaries
G Elser
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. The document is available on the GCIG website. Gabriele informed the only change she has been informed of is change of address for SGCTG and this change will be made shortly.

Action Points:
- Groups should check details are correct and update Gabriele accordingly of any changes

4. Translational Research
C Amos on behalf J Martyn
The ANZGOG group have taken the lead in moving this project forward. A checklist has been developed for the use of GCIG groups in the development of tissue consent forms. The checklist will summarize the basic principles required in tissue consent forms and act as a template for guidance to form trial specific documents. An updated checklist will be circulated shortly. Plan to have a teleconference over the next few weeks to discuss country specific practices. Following groups expressed interest in being involved in this: EORTC, SGCTG.

Action Points:
- Updated checklist to be circulated and teleconference to be organized shortly.

5. Education /Guidebook
R De Pont
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. Guidebook will be made available on the GCIG website.

At a previous meeting, concerns were raised 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 is a requirement for large randomized trials. It was suggested that an appendix to the guidebook be made to cover this issue.

Jim Paul prepared a draft appendix, which was circulated to the group for discussion. The document sets out a framework of minimum requirements for

Data Monitoring Committees for GCIG studies in addition to this it was suggested a detailed DMC charter should be drawn up also. Following discussion changes and additions to the document were suggested; Jim will redraft the appendix and circulate prior to the next meeting.

Action Point:

- Jim Paul to redraft data monitoring committee appendix and bring back to next meeting.

6. Intergroup Agreement

Most groups are now using the intergroup agreement. 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. At the next meeting in October MRC group will bring points from ICON 7 agreement.

7. GOG Electronic Data Capture Demo
B Stonebraker

Nathalie was thanked for CALYPSO demonstration at the last meeting. Anyone wishing a copy of the presentation should contact Claire.

Betty gave a demo of SEDES (Statistical and electronic data entry system). A copy of Betty's presentation is attached at the end of these minutes. Key aspects of the system were as follows:-

- SEDES built in-house.
- Individual patient diaries generated.
- Real time data quality checks.
- Pre-filled fields for specific protocol agents.
- All forms CDE compliant.
- Auto fill of baseline tumour details on subsequent assessment forms.
- Can modify diary to accommodate delay.
- Expected toxicities pre filled, but can add other toxicities.
- Back end QC checks on data consistency run daily.
- Time limits on resolving queries (14 days); thereafter query letter sent.
- The system includes monitoring tools and summary reports for Data Co-ordinator.
- Specimen consent recorded in system. Email notification to biobank / translational scientist.
- QOL forms are scanned into the system centrally
- To facilitate monitoring patients charts are printed out
- The system has changed the work focus at the data centre from data entry to training/ support

The system has proven to be very popular. The goal is to allow data entry for all GCIG studies (not being used so far).

Updates given from each group on what stage they are at in relation to EDC:

- MRC one study electronic.
- RTOG piloting EDC on follow-up forms. Also looking at patients filling QOL forms on line depending on computer literacy of population.
- AGO mainly paper- experimenting with teleforms.
- NCIC two studies purely electronic – still early days.
- NSGO still mainly paper.
- ANZGOG 100% electronic.
- SGCTG still paper.

Monica highlighted how it will be helpful for groups to share experiences of commercial solutions and requirements specifications in relation to electronic data capture at subsequent meetings.

Jim reported that the SGCTG had recently participated in the early pilot of an electronic remote data capture system. This was the culmination of a project co-ordinated by the NCRI to identify a suitable commercial package to support academic cancer clinical trials in the UK. Although no formal report on this project had been issued, Jim thought the conclusion would be that no suitable system had been identified. The SGCTG group was also now participating in another project to identify a suitable system, but this project was an initiative among Scottish clinical trials units.

Action Point:

- Jim Paul to try to obtain agreement to circulate the requirement specifications for the eRDC project that the SGCTG had participated in to the group

8. GCIG Specific Study issues

Brief updates given on GCIG trials by each group:

- EORTC 55971 neoadjuvant trial has now closed to recruitment.
- CHORUS (MRC) – currently 267 patients recruited.
- SCOTROC 4 (SGCTG) (1st line Catboplatin) ANZGOG participating in study. Currently 636 patients recruited.
- ICON 5 (MRC) presented at ASCO 2006. Final manuscript being prepared.
- JGOG Clear Cell Carcinoma Study. Target 450 - currently 54 patients recruited in Japan.
- ICON 7 (MRC) (1st line Avastin)– – currently 58/1520 patients recruited.

- GOG 218 (1st line Avastin)– currently 370 patients recruited of target 2000 (but this target to be reviewed)
- EORTC Tarceva trial – 450 patients recruited to date.
- OV05 (CA 125 study) – 1042 patients registered.
- CALYPSO (GINECO) – 850 patients recruited to date.
- ICON 6 (2nd line AZD) to open end of July / beginning August, for first phase.
- AGO (DESKTOP–II) (Evaluation of predictive factors for complete resection in platinum sensitive relapse) – 56 patients recruited to date. Aim to register 200 to obtain 120 with a positive score.
- ASTEC (MRC) Endometrial trial. Completed. Results of EBRT comparison presented at ASCO 2007 alongside NCIC CTG EN.5
- NSGO 9501/EORTC 55991. Endometrial trial. Completed. Results being presented at ASCO 2007.

9. Any other Business

– Monitoring issues to be discussed at operations subgroup.
– Claire has resigned from position of facilitator of the harmonization group Gabriele Elser has kindly agreed to take over the position. Thanks to Claire for her work with the group over the last few years.

10. Future Directions:

– Discussion on career options for young people to have placements/exchange with other GCIG groups. To be discussed within groups how this might be done

Next meetings

- October 2007 Berlin ESGO
- June 2008 Chicago ASCO

11. Meeting Adjourned

Respectfully submitted,

Karen Carty and Jim Paul

Operations/Data Management Group

Essential Documentation

- Bénédicte gave a follow-up regarding essential documents needed before trial start.
- A discussion was started about different practices regarding clinical trial insurance in US and Canada. It was discussed if a statement should be developed for Intergroup trials, that covers the differences about their insurance system.
- Financial Disclosure Statement (FDS) – there is a wide variation of different forms regarding FDS are used in GCIG trials. This is mostly trial specific, and often when a pharmaceutical company is closely involved - their forms are mostly used.
- Contract with hospitals/sites – it was realized, that groups handle this issue different. In groups like GOG this is covered within their membership elements and membership contracts; in other groups it is only needed for IND-studies, and others have that combined with the investigators contract.

These issues seemed to re-discussed at the Berlin meeting.