GYNAECOLOGIC CANCER INTERGROUP (GCIG)
Harmonization Working Group

November 3rd, 2005, Paris

MINUTES

	PRESENT:	ABSENT:
EORTC:	C. Coens G. Berthe	
NCIC CTG:	M. Bacon E. Eisenhauer	
AGO:	G. Elser Brittinger	
SGCTG:	K. Carty J. Paul	
GOG:	B. Stonebraker, M. Brady	
NSGO:	K Bertelsen & R DePont	
MRC:	C. Amos AM. Swart	
ANZGOG:	K. Scott	
SWOG:		
RTOG:		
GINECO:	Votan & LeFur	
GEICO:	Gonzalez	
GOG-J:		Akahash
GONO:		
NCI US:		
MaNGO	R. Fossati	
MITO:	Pignata	
AGO Austria:	Ulmer	
Website:	M. Schoenfeldt	

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

2. **Minutes, May 12, 2005 – no corrections**
   Motion: M. Brady; second: AM. Swart; approved – all
   Volunteer minute-taker: AM Swart

3. Updates to Summaries
G.Elser
Gabriele reviewed the status of the group summaries. The website will have the revised summaries including the GEICO update.

4. Randomization
Val Gebski circulated a document: **Validation of Adaptive Randomisation Schemes by Re-randomisation in Clinical Trials.**
Discussion of randomization issues:
There was some discussion about the validation of randomisation by minimisation following recommendations from the regulatory authorities. It was noted that some groups (MRC, GOG and JGOG) do not use centre as a stratification factor. This discussion was continued in the statisticians group meeting.

5. Translational Research
K Scott (Sian Munro)
The ANZOG group took the lead on coordinating a specimen consent and information sheet for translational research. They received sample forms and information sheets or guidance documents from most groups. A sample GCIG consent form and information sheet was circulated before the meeting. There were many issues raised such as:

- Open ended versus project specific consent.
- Whether information would be fed back to the participants if there were clear evidence of findings of medical importance.
- Is a letter confirming the destruction of your samples standard in all countries?

After much discussion it was concluded that due to a large variation in forms and legal requirements a list of essential elements for the forms with mandatory and optional sections would be a more practical solution for the group.

- Action point: Please send any outstanding template forms to Kathleen.
- Action point: ANZGOG to circulate a list of essential elements and suggested wording, which will be reviewed at the next meeting.
- Action Point: Corneal Coens will liase with the Translational studies group.
- Action Point: Monica Bacon will liase with the rare tumour group regarding a consent form.

6. Guidebook

NSGO circulated the updated version of the guidebook at the meeting.

- Action Point: The guidebook will be sent out electronically
- Please send any comments or suggestions to Rene DuPont.

7. Intergroup Agreement

Ann Marie Swart and Brigitte Nadeau reported back that the circulated agreement was currently being used in the GINECO coordinated CALYPSO trial.

- Comments were made that there is no form checking and that collaborating groups act as mailboxes for forms only.
- Monica Bacon reported back from the Executive committee meeting. The committee had endorsed the agreement with a few minor reservations concerning the intellectual properties (IP) section.
- It was further discussed that some countries had difficulties signing contracts with sections containing IP. This will need to be addressed on a trial-by-trial basis.

8. Neurotoxicity Coding

After review the chosen neurotoxicity grading system was the GOG toxicity questionnaire NTX1-4. An example from GOG protocol 172 was distributed at the meeting. These should be used and a validation paper is soon to be published.

9. Common Data Elements

There was no update to report on.

10. CTCAE Version 3

Monica Bacon informed the group that in preparation for the alert on IP therapy in ovarian cancer, specific terms and grades for likely toxicities need to be addressed. The toxicities could then be recommended to be incorporated into the CTCAE Version 3. It was suggested that a list of IP toxicities be compiled.

- Action Point: Monica Bacon to update at the next meeting.

11. GCIG Specific Study issues

Meetings for the GCIG trials CALYPSO, ICON6 and ICON7 trial took place during ECCO. The feedback from the group was that these were very useful and that it was helpful to have proposals for the development of the trials outlined so that decisions could be made during the meeting.

- Action Point: Ann Marie Swart will write a summary of how ICON6/7 has been developed within the GCIG group.
- Monica Bacon also made a plea that trial meetings do not overlap with GCIG meetings. Also that reply forms should be coordinated by one person from each group.

12. Future Direction:

- Electronic data capture
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Next meeting

- June 2006 Atlanta following ASCO
- October 2006 Santa Monica IGCS

13. Meeting Adjourned

Respectfully submitted,

Claire Amos & Monica Bacon