GYNECOLOGIC CANCER INTERGROUP (GCIG)

HARMONIZATION WORKING GROUP

MAY 12, 2005, 1:00 P.M. – 5:00 P.M., ORLANDO

MINUTES

	PRESENT:	ABSENT:
EORTC - GCG:	-------	I. Teodorovic, C. Coens
NCIC CTG:	M. Bacon	J. Pater
AGO - OVAR:	G. Elser, A. Reuss	-------
SGCTG:	K. Carty, J. Paul	-------
GOG:	B. Stonebraker, M. Brady	-------
NSGO:	K. Bertelsen, R. DuPont	-------
MRC/NCRI:	A.M. Swart	M. Parmar
ANZGOG:	B. Cakir, V. Gebski	-------
RTOG:	D. Grant, K. Winter	-------
GINECO:	B. Votan, B. Nadeau	-------
GEICO:	-------	A. Gonzalez
J - GOG:	E. Aotani, K. Fujiwara	-------
NCI US:	M. Schoenfeldt	-------
AGO – Austria:	-------	P. Speiser
Guests:	M. Bookman, P. DiSaia	-------

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

2. **Minutes, October 1, 2004 – approved**
   Minuter today – B. Nadeau

3. **Facilitator Replacement –** MRC/NCRI next meeting.

4. **Group Contacts and Summaries** Elser
   - Status of document reviewed.
   - Groups reminded to send missing info and maintain up-to-date.
   - Discussion re: randomization techniques (block versus minimization). Gebski will follow up on this.

5. Liaison with Translational Research Working Group

- Coens was performing this liaison function. No report provided.
- Discussion re: complexities of specimen consents; ANZGOG reps will follow through.
- Ovarian Cancer Consensus statement #12-C5 circulated and discussed:

12-C5: How to integrate translational research in clinical trials in ovarian cancer?

- Translational research should be considered in the planning of future clinical trials.
- Integration requires harmonization of consent processes and standardization of data bases, including minimum data sets, and specimen banks, including central pathology review.
- Regulatory aspects of shared samples need facilitation.
- GCIG trials should have early consultation with GCIG translational research group.

Level of Acceptance: 13/13

The GCIG has gathered a large experience within its translational research and harmonization groups, with the latter having established uniform consent forms and defined regulatory issues associated with sample sharing. Both working groups could offer support if other study groups decide to include translational research in large randomized trials.

6. **Education – Guidebook Development** Bertelsen/duPont

- Discussion re: original goals of this guidebook and its similarities/differences to the Intergroup Agreement.
  DuPont will follow through.

7. Intergroup Agreement/Database Sharing Swart

- Comments were received and integrated; current version of the document circulated. Discussion led to several very minor additional revisions to be done.
- Endorsement from the Executive Board will be requested.

8. Neurotoxicity Grading/Reporting Paul

- Review of past activity and update of current status.
- Discussion resulted in resolve that once published, these criteria will be recommended for adoption by GCIG from Harmonization to Executive Board.

9. CTCAE version 3 Bacon

- Review of the evolution and facility of this criteria. Most groups are using this in current trials.

10. Common Data Elements – Gyne CDEs Bacon/Brady

- CDE update provided by C. Valmonte was shared.
- Review of evolution and function by Brady.
- Discussion resulted in continued enthusiasm that GCIG be represented on the Gyne CDE Committee; particularly to influence additions of surgical variables. In the meantime, Harmonization group will develop its own gyne surgical CDEs.

11. <u>EU Directive Sub Group</u> has not yet met.

Some general discussion ensued re: the EU Directive website and influences to study drug supplies.

12. GCIG Study Issues

- Password protected area for study “war wounds” is not yet available on the GCIG website. Schoenfeldt will follow through.
- ICON 7 meeting May 16/05.
- CALYPSO launch May 15/05.

13. Next Meeting: November 3, 2005, Paris.

14. Meeting adjourned.

Respectfully submitted,
Monica Bacon