# GYNAECOLOGIC CANCER INTERGROUP (GCIG)
## Harmonization Working Group

## October 1, 2004, Caledonian Hilton Hotel, Edinburgh

## MINUTES

| | PRESENT: | ABSENT: |
|---|---|---|
| EORTC: | C. Coens | I. Teodorovic |
| NCIC CTG: | M. Bacon | J. Pater |
| AGO: | J Rochon, G. Elser | ------- |
| SGCTG: | A. Hay, J. Paul | ------- |
| GOG: | M. Bookman | B. Stonebraker, M. Brady |
| NSGO: | R. dePont Christensen, G Andersen | K. Bertelsen |
| MRC: | A.M. Swart, W. Qian | ------- |
| ANZGOG: | ------- | H. Dhillon, M. Stockler |
| RTOG: | ------- | D. Grant, K. Winter |
| GINECO: | B. Votan, N. Le Fur | ------- |
| GEICO: | A. Gonzalez | ------- |
| J-GOG: | ------- | E. Aotaini, M. Takeuchi, |
| NCI US: | Mason Schoenfeldt | B. Meadows |

**1. Welcome and Introductions** **A. Hay**

**2. Minutes, June 3, 2004**

- No corrections.
- Motion: M. Bacon; Second: J. Paul; Approved: All.

**3. Status of Group Contacts and Summaries**

- Some summaries remain incomplete for a number of the groups.
- **Agreed deadline of end of February 2005 for providing this information.**
- Following discussion regarding randomization techniques it was agreed that further information on this issue should be added to this document (see item 4.6 of minutes).

**Action: G. Elser**

## 4. Prior business from Previous Meetings

### 4.1 Collaboration - Report from Translational Research (TR) Working Group

- Collection of biological sample consent forms - consents only received from EORTC, MRC, NCIC-CTG and SGCTG. **Remaining groups to forward sample consents by end of November 2004 with the target of producing a template minimum IC document in 2005.**
- Monica confirmed that at the recent Consensus Workshop there were a number of priority issues identified regarding translational research (TR) that overlapped with our discussions. These were:
  - TR should be included where possible in trials;
  - Standard of informed consent;
  - Standard of date collection;
  - Sharing of samples.
- The issue of withdrawal of consent was discussed and most groups confirmed that they destroy samples where IC has been withdrawn as opposed to return of samples.
- To be discussed at next meeting.

**Action: C. Coens**

### 4.2 Guidebook Development

- Current version circulated by e-mail prior to meeting.
- It was agreed by all that the purpose of the guidebook is primarily for new groups joining GCIG. It should be a checklist that pulls out the truly essential elements of GCIG studies.
- Add access to drugs and discussion with companies to the guidebook.
- Additional comments to NSGO members.
- To update at the next meeting.

**Action: NSGO Members**

### 4.3 Database Sharing/Intergroup Contracts

- Following comments, Anne-Marie to update current version and send to Mason for circulation to Harmonization members. **Deadline for comments by end November 2004.**

**Action: MRC Members**

### 4.4 Neurotoxicity Grading/Reporting

- Jim Paul summarized work/review completed to date.
- At the last meeting it was agreed that the recommendation for a standard patient question tool would either be the SGCTG questionnaire or the GOG Fact NTX. A final decision will be made once the GOG Fact NTX

has been through GOG review process and published. Mark Brady to update Jim when this has taken place.

- Translations of scales were discussed. It was suggested that the EORTC QOL Working Group could advise on how this should be managed when required.
- To update at the next meeting.

**Action: SGCTG Members**
**Mark Brady**

**4.5 Common Data Elements (C.D.E.s)**

- The International Gynaecology C.D.E. Committee has not convened since these were developed. It is still hoped that Jim Paul and Max Parmar could be on the Committee to represent the European perspective. Monica will keep Jim/Max updated re this.
- It was agreed that it is important for C.D.E.s for surgery to be in place – they currently don't exist in Gynae C.D.E.s.
- It was commented that website is not very user friendly.
- It was agreed that there should be an instruction included in the Guidebook regarding C.D.E.s (agreed set of C.D.E. compliant CRFs for GCIG studies).
- Samples of the GOG C.D.E. compliant forms were circulated for review prior to the last meeting. Any additional comments on these should be sent to Jim by the end of the year.

**Action: M. Bacon / M. Schoenfeldt**

**4.6 Randomization Techniques**

- The issue of randomization techniques was raised following a new guideline suggesting the minimization technique was inadequate.
- It was agreed that it would be helpful to add a detailed summary of how the randomization process works for each of the groups to section 7 of the Group Contacts and Summaries document. **Action: G.Elser**
- To be discussed at next meeting.

**Action: C. Coens**

**4.7 Common Toxicity Criteria, Version 3**

- Activated November 2003.
- EORTC now use for all studies.
- Mapping to MEDRA - can now map to short term (as well as long).
- Monica confirmed that any comments on V3 should be sent to Ann Setzer who would welcome these.
- Further update to be given at next meeting (if any).

**Action: M. Bacon**

**5. New Business**

- It was previously agreed that the group could be used as a discussion forum for EU Directive issues. Leave on agenda for future discussion.
- It was agreed that the GCIG website would be the ideal place for GCIG study issues to be discussed. This would be a password protected area for study "war wounds" to be discussed. Mason confirmed that he was working on a members only area for the website at present but that this could be put in motion when this area is available. **Action: M. Schoenfeldt**

**6. Future**

**6.1 Action plans/goals were summarized.**

- There have been no volunteers for the position of Facilitator of the Harmonization Group to date. Mason agreed to be the central point for dissemination of information until a replacement Facilitator is in place.

**Action: M. Schoenfeldt**

**6.2 Next meeting**

12/13 May 2005, Orlando, USA.

**7. Meeting Adjourned**

Respectfully submitted,

Andrea Hay