GYNAECOLOGIC CANCER INTERGROUP (GCIG)
Harmonization Working Group

October 18th, 2006, Santa Monica

MINUTES

	PRESENT:	ABSENT:
AGO	G. Elser, A. Reuss	
AGO-Austria	J. Ulmer	B. Volgger
ANZGOG		J. Martyn, V. Gebski
EORTC	U. Bethe	C. Coens
GEICO		A. Gonzalez
GINECO	B. Votan, N. LeFur	
GOG	B. Stonebraker, M. Brady	
GOG-J	E. Aotani, F. Takahashi	
MaNGO		R. Fossati
MITO		S. Pignata, F. Perrone
MRC/NCRI	C. Amos, W. Qian	
NCIC CTG	M. Bacon, H. Mackay	
NSGO		G. Andersen, R. DePont
RTOG		K. Winter, D. Grant
SGCTG	K. Carty	J. Paul
Website	Mason Schoenfeldt	

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

2. Minutes, June 6, 2006 – no corrections

Motion: M.Bady; second: M.Bacon; approved – all

3. Volunteer minute-taker: G. Elser

4. Group Contacts and Summaries

G.Elser

The group contact and summaries list was circulated.
Since last update following changes were done:
ANZGOG Burcur Cakir was replaced with Julie Martyn
NSGO Kamma Bertelsen was replaced with Gerda Anderson
MaNGO- group details still outstanding
On the GCIG website the last version of the document dated on Oct-02-2006 is available.
Action Points:

- MaNGO Group to send group details to Gabriele

5. Translational Research/Specimen Consents
M. Bacon for J. Martyn
The ANZOG group has taken the lead in moving this project forward.
A checklist created by the team of ANZGOG, mainly Julie and Kathleen, was sent out to the group for reviewing and discussing with the Translational Research teams.
Within the meeting the following issues came up for further discussion:

- adding of a section with regard on commercial use
- Storage duration. EORTC SOP includes a section like " storage as long as analysis can be done with a sample/tissue"
- What happens with human material after an Intergroup is finished. Who will give the guarantee, that material will be destroyed and further not permitted tests will be done without the consent of our patients?
- Other obstacles are: national laws (e.g. Austria is not allowed to send out samples outside the EU without permission of the data protection law office), Canada – Health Care Canada is extremely strict in their obligations.

There is an existing reference document at the EORTC which included most of the specific requires of countries, which are working with the EORTC

Action Points:

- Each group should have a carefully look on the checklist again and send all comments and questions to ANZGOG
- Corneel Coens, who was involved in the really first discussion should contact Julie Martyn to exchange information.
- Ulli Bethe is asked to provide the members of harmonization group with the EORTC reference document

6. Education /Guidebook
As representatives of NSGO couldn't attend the meeting, this point was excluded and will be presented at the next meeting

Action Point:

- Present at next meeting (June 2007).

7. Intergroup Agreement (Feedback)
All attendees agreed about the usefulness of this agreement. Most groups are using it in their trials (GINECO, EORTC, MRC/NCRI ICON7, JGOG for the Clear Cell Cancer Study).
It would be helpful, if groups could send their country specific parts to AnnMarie to update the agreement (e.g. AGO has often problems with the intellectual property part)

Action Point:

- AGO to send translation of intellectual property part to AM

8. Neurotoxicity Grading/Reporting Update
Mark Brady informed the group that the paper is accepted for publication.

Action Point:
- Mason to inform GCIG group when publications comes up

9. CALYPSO Website Demonstration
Nathalie le Fur presented the structure of the CALYPSO website and pointed out the different parts including:
- Participating Groups – Group administration issues
- Investigator tasks
- Other issues, e.g. definition of essential documents, initiation and activation of sites, data/queries, safety reporting and much more.

It would be helpful, to send out an evaluation form at the end of the study to participating investigators and study coordinators and nurses.

Discussions came up, as nearly every group is using or is current developing their own e-CRFs. EORTC is working with its own system, NCI CTC is working to have establish a RDC system in 2008, JGOG is also working on web-based documentation. MRC/NCRI have a pilot Colerectal trial using EDC.
On the other hand, the influence of industry should not be underestimated, mainly in registration trials.
Following discussions, it was realized that there is no unit template, no standard for Intergroup trials available. Questions about the need of development of core elements in e-CRFs as well as the need of any checklists and guidelines came up.

Action Point:
- Nathalie to send out a questionnaire to survey the groups activities on RDC
- Bette volunteered for the GOG system to be demonstrated at the next meeting

10. GCIG Study issues
Brief updates given on GCIG trials by each group:
- GOG – Ovarian Cancer: 1st line Avastin trial – 200/2000 pts
- new I.P. trial in development
- ICON7 (MRC) 1st line: first patient in, October 2006; other groups (NSGO, GINECO, GEICO, NCIC and AGO) following after regulatory issues will be solved, early in 2007.
- ICON 6 (MRC) 2nd line trial with AZD; first patient awaited February 2007 (MRC and NCIC)
- ASTEC (MRC NCIC) Endometrial trial, 1409 pts randomized; surgery trial being submitted for publication and the radiotherapy trial with EN.5 has been accepted at ASCO 2007
- CHORUS Phase III feasibility trial, 200 pts at present, ongoing recruitment

- EORTC 55971 neoadjuvant trial – 720 pts in, will be closed end of 2007
- EORTC Tarceva trial – EORTC 200 patients recruited, ongoing the next 12-15 months.
- JGOG – Clear Cell Carcinoma Study, 1st line trial in ovarian (participating groups GOG and UK sites). 450 pts planned.
- CALYPSO (GINECO) – 464 patients randomized, end of recruitment expected summer 2007.
- AGO –OVAR 7 (TC-TOP vs TC) published, OVAR 9 in follow-up – next interim analyses spring 2007
  DESKTOP II (Evaluation of predictive factors for complete resection in platinum-sensitive recurrent ovarian cancer) - just started; participating groups AGO-Austria, GINECO and MITO

11. Monitoring Issues in GCIG Trials

It was agreed, that each group should bring their Monitoring Issues for discussion at the next meeting.

12. Next meetings:

June 4-5, 2007 Chicago ASCO
October 27-28, 2007 Berlin ESGO

Operations/Data Management Group

Essential Documentation

B. Votan

Before the meeting a survey was send out by Bénédicte Votan asking for templates in essential documents used by the groups.
As a conclusion of this survey and the discussion within the group it was pointed out, that harmonization in EDs naming should be adjusted.
Follow-up of this issue will be at the next meeting.

Respectfully submitted, Gabriele Elser