



GCIG-HARMONIZATION COMMITTEE

Sept. 8, 2011

AtaHotel Executive, Viale Don Luigi Sturgo, 45, Milano, 20154, Italy

MINUTES

Present:

Members:

AGO-OVAR:	S. Polleis, A.Reuss
ANZGOG:	J.Martyn
COGi:	A.Buchin
DGOG:	K.Adema
EORTC:	A.Negrouk
GCIG:	M.Bacon
GEICO:	F.Nepote
GINECO:	N.Le Fur, B.Votan
GOG:	M.Brady, B.Stonebraker
KGOG:	E-K.Park, J-S.Kim
MITO:	J.Bryce
MRC/NCRI:	L.Farrelly
NCIC-CTG:	A.Hiltz
NCI-U.S.:	G.Thomas
SGCTG:	J.Paul

OPERATIONS /DATA MANAGEMENT AND STATS

1. Welcome and Introduction:

J. Martyn (JM) opened the meeting, welcomed and introduced participants. M Bacon (MB) introduced that Declaration of Conflict of Interest as first order of business in our meetings. No participants declared any conflict of interest. Addition to agenda requested by MB regarding trial funding and site resources (possible survey), and all agreed to discuss during the Operations only session

2. Approval of minutes

Minutes of meeting June 2, 2011 (Chicago) unanimously approved (Motion by B Stonebraker (BS) seconded by A Buchin (AB)

3. Minuter: J. Bryce (JB) minuter for this meeting

4. Chair and cochair nominations: New Chair and CoChair Harmonization group will be assumed at next meeting in Chicago May 2012.. JB will become group Chair. Bette Stonebraker was nominated as CoChair, and was unanimously approved to this position by the membership present at the meeting.

5. Trial Updates /Bibliographies/website issues

M. Powers (MP) sent out a trial list that needs to be updated by members, including accrual information. This list will be made available on a secure portion of the GCIG website. MP will circulate list by email as a reminder to those who have not yet responded.

Bibliography does not have password protection, and full protocols were removed at this time.

A discussion ensued about what the group would find useful on the website, and the following suggestions were presented:

- Links to the cooperative group websites
- Password protected areas
- More up to date trial information, particularly about accrual, groups participating
- Templates of study documents that include minimum requirements that majority of group adheres to/requires.
- Guidebook access (password protected)

6. Ongoing business

a. **Group contacts and summaries:** JM is continuing work on this. The following groups have responded MRC,SCOG,GEICO, EORTC, GINECO, MITO, ANZGOG, NCIC, NSGO. JM will follow up by email for missing responses.

b. **Translational research and tumor banking:** translational research and tumor banking were discussed together

i. **Translational research** JM reminded that checklist for translational research is part of guidebook and will include what is required for inclusion in the translational research consent form. Please use this form and provide feedback. JM also discussed need for mechanisms of communication between translational and harmonization working groups, as this issue spreads across disciplines and tumor sites. NLF and JM have agreed to attend the translational working group meetings on behalf of Harmonization. JM requested to executive board to evaluate schedule to permit attendance at both.

ii. **Tumor banking** discussion led by N. LeFur (NLF) who presented the issues (see attached presentation slides) a. Many issues were discussed, of high priority was ownership of samples, and types of tissue banking (internal, virtual, external, etc), patient consent specificity, intellectual property rights, contracts, and future use of specimen. Information regarding tissue samples, and the need for assuring clinical information of patient be kept separate from samples. Anastassia Negrouk (AN) discussed the EORTC experience with

defining logistics, contracts for multiple labs and/or central labs and SOPs upfront in each trial. To guarantee consent review, AN and NLF will propose a checklist for verifying adherence to use of specimen consistent with actual patient consent.

c. Nursing studies & potential:

- i. OV-21 (MB) recruiting
- ii. Symptom Benefit (JM) recruiting, and all interested or participating groups invited to attend study meeting being held later today
- iii. MITO-12 (JB) recruiting.

d. QoL instruments not discussed, RTOG not present

e. Remote Data Capture archiving: J. Paul presented a Summary of EDC and approaches to archiving of electronic data by GCIG groups (see attached). Many in house or different commercial products being used, and no single common system is in place for data sharing.

f. Updates on CDEs and CTCAEv4: No further updates or discussions on these topics.

7. Strategic Planning: MB led discussion on Operations mentoring for groups new to GCIG. A “welcome” package of documents and/or an online tutorial (guidebook, minutes, etc) to be provided to the operations representative, and each new operations member to be paired with an experienced group member. F. Nepote (GEICO) has volunteered to mentor GICOM (Mexico).

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8. Next meeting: to be held in Chicago, May 31 and June 1, 2012

Operations/Data management issues:

1. Ongoing Business.

- Policies/processes- for protocol deviations and violations- quality : S Polleis, AGO presented slides regarding definitions and procedures for protocol deviations used by AGO. Discussion held regarding a template for common definitions and general reporting procedures or responsibilities that should be included in an intergroup trial . JB and AH will propose how to include in GCIG documents. (see attached slides)
- EU Directive updates presented by AN (see attached slides)
- Group specific appendix format being modified by Laura Ferrelly and to presented next meeting
- JM introduced issue of promotion of non profit trials in the intergroup. Discussion about the high work load for trial start up with limited site resources.

2. Next meeting: to be held in Chicago, May 31 and June 1, 2012

Meeting adjourned.

Respectfully submitted,