GCIG-HARMONIZATION COMMITTEE

December 1, 2012

Holiday Inn, Leiden , the Netherlands

MINUTES

Present:

Members:

AGO-OVAR:	SandraPolleis, AlexanderReuss
AGO-Austria:	Regina Berger
ANZGOG:	JulieMartyn
COGI:	Anthea Buchin
DGOG:	Karen Verhoeven-Adema
EORTC:	AnastassiaNegrouk
GCIG:	Monica Bacon
GEICO:	Frederico Nepote
GINECO:	Benedicte Votan
GOG:	Mark Brady, Bette Stonebraker
ICORG:	Anna Shevlin
JGOG:	Eriko Aotani, Tetsutano Hamano
KGOG:	Byung-Ho Nam
MITO:	Jane Bryce
MRC/NCRI:	Laura Farrelly, Andrew Embleton
NCIC-CTG:	DongShongTu
NSGO:	Gerta Anderson
PMHC:	ChantaleBlatter
SGCTG:	Jim Paul

OPERATIONS /DATA MANAGEMENT AND STATS

1. **Welcome and Introduction:**
   Jane Bryce (JB) welcomed new members and visitors. Monica Bacon (MB) introduced the Declaration of Conflict of Interest as the first order of business in our meetings. No participants declared any conflict of interest. Welcome to Chantale Blatter representing new GCIG member Princess Margaret Hospital Consortium
2. **Approval of minutes**
   Minutes of meeting May 31,2012 (Chicago)will be corrected to reflect 5e.vi. should be Val Gebski, and 5e.viii should be EQ5D. The corrected Minutes were

provisionally approved pending the updated attendance list to be completed by Sonja.Motion by AntheaBuchin seconded byFredericoNepote (FN).

3. **Minuter:** Bette Stonebraker (BS) minuter for this meeting

4. **Website Issues and Updates**
   - **a.** MB presented the Website on behalf of Webmaster Sonja Easley who was unable to attend.
   - **b.** It is noted that the GCIG Website has been updated by Sonja.
   - **c.** Discussion took place regarding a having a password protected area for the purpose of posting slides or documents for limited viewing. It was determined that documents and slides will be posted publically, unless requested by the author not to be published.
   - **d.** All Harmonization Members are asked to continue to cruise and critique the Website and provide feedback to Sonja.

5. **On-going business**

   - **a. Group contacts and summaries**: JM is continuing work on this. Several groups still need to submit summaries: Dutch, COGI, JCOM, MANGO, ACRIN, and PMHC. The rest of the Groups are again asked to review, update and send changes to Julie. Deadline for these submissions is January 1, 2013.

   - **b. Guide Book**:Karen Carty was unable to attend this meeting but work on this is ongoing. It was felt that the Research Agreement template needs updating. A subcommittee was formed to assist Karen Carty. Anastasia Negrouk (AN) (EORTC) and GINECO members, Nathalie Le Fur and Brigit Voltan will join this subcommittee. Other interested members should contact Karen. Issues of "sponsorship" and template vs. guidelines will be addressed.

   - **c. Translational research and tumor banking:**It is noted that the Checklist has been submitted to the TR Committee and we are awaiting response from the Committee. AN will attend the Meeting to facilitate getting response from the Comm.to insure it covers the needs of the group.

   - **d. Nursing studies (aka Non-treatment trials)& potential:**
     - i. OV-21 (MB) Nursing complications -on-going
     - ii. Symptom Benefit (JM) recruiting, should close in 2-3 months collecting baseline, FU, pt. reported outcomes.
     - iii. MITO-12 (JB) –nearing closure, will close in segments; collecting sentinal events, describing symptoms as predictors of ov ca; describe time interval of sentinal events.

   - **e. QoL instruments** Kathryn Winter unable to attend. It was noted that Symptom Benefits WG may already be compiling a list of Instruments available and utilized. Harmonization will defer to them at this point. JM will attend the WG to facilitate communication and offer input.

   - **f. Mentoring** FN had slide presentation on his experience as a mentor:

i. Tools used -Current status of Harmonization on Website including Guidebook, Appendices, other information on the Website
ii. Noted huge Welcome packet lacks information about mentoring.
iii. Issues appear at first meeting
iv. Needs of new members from existing groups differ than those from new groups.
v. All members are asked to re-review own contacts and summaries as well as others for use in mentoring.
vi. Suggestion made to post Frederico's slides as mentoring tool.

6. **New Business**
   a. Quality Assurance proposal set forth by Executive Committee presented by JB for discussion. The following points emerged from the discussion and will be presented to Executive Committee in their meeting on Dec 2
      i. Basic principal of Harmonization Comm includes QA Program
      ii. 3 documents that support QA are the Intergroup Agreements, Group Specific Appendices, Group summaries
      iii. Trial specific monitoring should be detailed in every protocol
      iv. QA policies should be described/updated in by each group in Group Summary

   b. Rare tumours
      MB advised that Nov 2013 GCIG day 1 will be Rare Tumours clinical trials and their working group plan to invite one Ops/DM to speak on operational & regulatory obstacles and one Stat to speak on Methodology obstacles.

7. ***GCIG Studies***
   a. SHAPE- looking to activate by July
   b. EO shared experience of JGOG as first-time lead group of the JGOG clear cell trial. .

8. **Future Meeting agenda item**
   a. Approaches to collecting data on International trials

9. **Next meeting:** to be held in Chicago, May 31, 2013

Operations/Data management issues:

1. **Ongoing Business**.
   a. **Common data elements**
   MB and BS reviewed the purpose of the CDEs that permit data analysis / data sharing / evaluation of results across studies.
   https://cdebrowser.nci.nih.gov/CDEBrowser/
   b. **Group Specific Appendix**
   LF has completed a draft of the GSA and presented the template to the group. review and send any further comments by 1 Feb. Final document will be posted on webpage

c. Intergroup agreement

KC unable to attend meeting, asked that all comments about intergroup agreement , particularly comments from those who have used it should be emailed to her by 1 Feb 2013, so the template can be update for next meeting

2. Pharmacovigilance requirements, lead group

LF a presented the pharmacovigilance reponsiblities of the lead group and participating group as addressed in the GSA. Standard and protocol specific definitions were discussed, and ICON 8 experience shared. New regulatory requirements according to EMA and FDA, in particular harmonization of annual safety reports in the form of Development or Periodic Safety Update Reports , and of the definition of SUSARs across continents were highlighted.

2 Roadmap ENGOT

BV presented the content of the roadmap for clinical trials document produced by the ENGOT group. Some of the highlights include type of sponsorship, communication flow, etc. The Operations group identified the need to have a liason with ENGOT, and the proposal of Gabriele Elser was unanimously approved by group. With Executive approval, Harm chair will formally invite for participation in future meetings

3 CCRN update

MB and JM reported on the cervical cancer research network. As this disease has high incidence in developing countries where the clinical research infrastructures are not always well established, there is ongoing work to help the sites that do not already have the support of a GCIG group. Focus has been on establishing a procedure for site selection and verification/assistance with basic quality assurance for sites to participate in GCIG cervical cancer trials.

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4 European Directive updates

AN informed group about new EU directive draft that has been proposed, expected to simplify and better harmonize some aspects of the approvals procedures for clinical trials in the EU. The directive is under evaluation and comments in the forms of amendments are being submitted. A final directive will likely not be issued before 2-3 years. The current proposal calls for one application via web to which all relevant information will be attached, this information will be sent both to CA and EC in one step. It is expected that “low cost” insurance should be made available, by Member States, for low risk trials. Further centralization via single websites for applications, safety reporting are proposed.

5 Lead Group Activity Matrix

JM has created a matrix that summarizes each group’s experience as lead group. Review and send any corrections or missing information to JM no later than 1 Feb 2013

6 Farewell

Gerta Anderson from NSGO is attending her last meeting at GCIG, she will retire April 2013. Special thanks for her steadfast and important contribution to the Harmonization and Operations Committee.

Meeting adjourned.

Respectfully submitted,
Bette Stonebraker