



GCIG-HARMONIZATION COMMITTEE

May 30, 2013

Hilton Doubletree Chicago, IL

MINUTES

Present:

Members:

AGO-OVAR: Sandra Polleis, Alexander Reuss
AGO-Austria: Regina Berger
ANZGOG: absent
COGI: Ashley Powell
DGOG: absent
EORTC: Anastassia Negrouk
GCIG: Monica Bacon
GEICO: Frederico Nepote
GINECO: Benedicte Votan, Nathalie LeFleur
GOG: Mark Brady, Bette Stonebraker
ICORG: Anna Shevlin, Brian Moulton
JGOG: Eriko Aotani,
KGOG: Byung-Ho Nam
MITO: Jane Bryce
MRC/NCRI: Nicole Gowfer, Andrew Embleton
NCIC-CTG: Andrea Hiltz
NOGGO: Maren Weller
NSGO: Tinne Kirkegaard
PMHC: ChantaleBlatter
SGCTG: Jim Paul, Karen Carty
China GOG: Ji Zhu
GICOM: Adriana Chavez-Blanco

Guests:

BIG: Carolyn Straehle, Amal Arahman
ENGOT: Gabriele Elser

Staff:

Dina Hess, Webmaster

OPERATIONS /DATA MANAGEMENT AND STATS

1. **Welcome and Introduction:**

Jane Bryce (JB) welcomed new members and visitors:

Welcome to Breast International Group (BIG) guests Carolyn Straehle and Amal Arahman. BIG was presented as 49 Academic Coop Groups and Data Centers worldwide, historically conducting large adjuvant trials. BIG recognizes the need to harmonize processes globally.

Gabriele Elserof AGO Study Group was also welcomed back as ENGOT liaison. This liaison established to avoid re-inventing established processes. ENGOT mission was presented.

Dina Hess from NCI US was introduced as the new GCIG Webmaster.

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

2. **Approval of minutes**

Motion and second to approve Minutes of meeting December 1, 2012 (Leiden) as submitted (Paul/Brady). Motion approved.

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

4. **Harmonization/Stats Overview**

a. Monica Bacon presented history of Harmonization Committee 2001-2013.

Highlights included:

- Group Summaries- Julie Martyn (ANZGOG) (owner)-send updates to Julie
- CTCAE versions 2 to 3 to 4 – endorsed by GCIG
- CDE's
- Common languages
- QOL roster- validation of QOL Tools
- Specimen collection checklist
- Guidebook developed 2002-now owned by Karen Carty(SGCTG)
- Visit all tools available on the Website

b. Mark Brady presented history of Stats Group. Highlights include:

- 1993 Elsinore Denmark 1st Intl Ov Ca Consensus Conf
- Where do we go from here? 1993 meta analysis to today
- Adapt to the way GCIG is developing new studies
- Develop harmonized stat guidelines and data elements, homogenized but distributed data collection procedures.
- Need to develop one system-how best to accomplish
- Consideration of not only collecting harmonizing data but how to analyze

c. Discussion ensued regarding unification of systems

d. Subcommittee formed to liase with Brady (Sandra Polleis, Andrew Embleton, Anna Shevlin)

5. **Website Issues and Updates**

a. Dina Hess discussed user friendly Harmonization page-members encouraged to view latest version

- b. Suggestions, revisions, etc. should be provided to Dina.

6. On-going business

- a. **Group contacts and summaries:** (ANZGOG) JM is continuing work on this. The Groups are again asked to review, update and send changes to Julie. Deadline for these submissions is June 30, 2013.
- b. **Guide Book:** (SGCTG) On-going. Feedback should be submitted to Karen Carty. KC will add link to Membership application.
- c. **Mentoring:** (GEICO) Federico Nepote presented all elements of New Member Welcome Package. Volunteers for mentoring: Andrea, Eriko, and Regina
 - i. Possible online tutorial to be developed
- d. **Quality Assurance:** Jane Bryce presented QA Plan as presented to the Exec Comm:
 - Responsibilities of Lead Group/Sponsor –monitoring, IDMC, participating group compliance, tools
 - Responsibilities of Participating Group-maintain participating group Trial Master File
 - Tools to include IG Agreement, Trial Specific Appendix
 - Responsibilities of every GCIG Member-QA Policy, Audit Plan, GCP compliance/ training, activity of lead group, activity of Group Sites,
 - Tools-Harmonization , GCIG Web page, summary sheet, online GCP training, summaries
 - Harmonization Comm Responsibility-finalize drafts, data collection, update mentoring, upload links, ongoing consideration of tools, retrospective surveys, prospective surveys
 - MB presented Exec Comm feedback from the presentation; suggestions and directions will be forthcoming from Exec to JB.

7. New Business

- a. Rare tumours- the upcoming brainstorming workshop will be first day of fall 2013 GCIG meeting in London. Ops and stats will be involved in sessions.
- b. Approaches to data collection on Int'l trials – Brady et al (4.d.)
- c. Response and evaluations issues (Bryce) –timing survey to be distributed.

8. **Next meeting:** to be held in London, November , 2013

9. **Adjournment to Ops/Stats breakout**

Operations/Data management issues:

1. Ongoing Business.

- a. Agreement template – questionnaire circulated; thanks to all who replied.
- b. Group Specific Appendix (MRC/NCRI) – per lead group requirements- could be attached as part of Intergroup Agreement
- c. TR Committee liaison report (GINECO)
 - i. Tumor Banking Checklist by Sept 1st
 - ii. How to manage w/clinical trial collections for purpose of trial
 - iii. Will GCIG oversee, hold onto, etc.—what level of governance?
 - iv. Biobank storage
 - v. Quality of sites, groups
 - vi. Respond to TR questionnaire by 6/30
 - vii. Funding difficulties
- d. Symptom benefit –no report
- e. Lead group matrix activity (ANZGOG)- to update
- f. CCRN update- SOP's forthcoming
- g. ENGOT liaison report- would like to use GCIG documents; suggestion to publish

2. New Business- deferred to November due to time constraint

- a. Insurance/Indemnity- Polleis
- b. Site staff – German Law-Polleis
- c. Trial closure letters- Stonebraker

3. European Directives-update provided by Anastasia Negrouk

4. Mentoring assignments:

- a. Federico-Adriana
- b. Sandra-Regina, Maren
- c. Bette-Ashley
- d. Laura-Nicki
- e. Chantale-Andrea
- f. Byung Ho Nam (KGOG Stats)-Ji Zhu (China GOG)

5. Meeting adjourned.

Respectfully submitted,
Bette Stonebraker