



GCIG-HARMONIZATION COMMITTEE

November 16, 2013

UCL Education Centre, London, UK

MINUTES

Present:

Members:

AGO-OVAR: Sandra Polleis, Alexander Reuss
AGO-Austria: Regina Berger
ANZGOG: Julie Martyn
COGI: Ashley Powell
DGOG: Josien Kant
EORTC: Anastassia Negrouk
GEICO: Absent
GICOM: Absent
GINECO: Benedicte Votan, Nathalie LeFur
GOG: Mark Brady, Bette Stonebraker
GOTIC: Sae Tsuboi
ICORG: Anna Shevlin,
JGOG: Eriko Aotani, Masahiro
KGOG: Byung-Ho Nam, Bomi Choi, JongSoon Kim
MaNGO: Roldano Fossati
MITO: Jane Bryce
MRC/NCRI: Laura Farrelly,, Andrew Embleton
NCIC-CTG: Andrea Hiltz
NOGGO: Maren Keller
NSGO: Tinne Kirkegaard
PMHC: Chantale Blattler, Dongsheng Tu
SGCTG: Jim Paul, Karen Carty
SGOG: Ji Zhu

GCIG: Monica Bacon

ENGOT liaison: Gabriele Elser

Webmaster: Michelle Powers for Dina Hess

3:30pm OPERATIONS/DATA MANAGEMENT

1. Welcome and Introduction:

- a. Jane Bryce (JB) welcomed members and visitors
- b. Publications and Travel support added as agenda items
- c. No participant declared any conflict of interest.

2. Approval of minutes

Motion and second to approve Minutes of meeting May 30, 2013 (Chicago) as submitted (Bacon/LeFur). Motion approved.

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

4. On-going business

- a. **Agreement Templates:** Update of changes presented (Carty).
Sponsor/ Legal Entity: Discussion regarding definition of responsibilities. Sponsor has all responsibilities; Need to specify to whom the sponsor delegates tasks or other responsibilities (i.e. 3rd party implications). Document should speak for itself. The section on Publication guidelines removed as Authorship policy already a GCIG statute.

Survey discussed-What tools are you using? Are you using the agreement? (Ask annually) Check essential documents checklist, Roles, Responsibilities

Biological materials added/Appendices; Removed intellectual properties.

Amended doc. to be sent to Webmaster for website posting.

- b. **Group Specific Appendix** (Farrelly)
Change title from Group Specific Appendix (GSA) to Group Specific Operating Procedures as optional title.
- c. **Translational Research Committee Liaison** (LeFur, Negrouk)
Ongoing-Defer report to Chicago
- d. **Symptom Benefit Working Group Liaison:** (Martyn)
No update. Study by ANZ/AGO/Canada of MOST being validated (500 patients). Discussion ensued of who owns copyright of MOST -GCIG vs. ANZGOG. Question deferred to Executive Committee.

QOL: Discussion of versions & translations available.
- e. **Lead Group Matrix Activity (PARTICIPATION)** (Martyn)
Document Presented, work continues and call for twice yearly updates, and availability on Harm page on website
- f. **CCRN Update presented** (Bacon)
Recap of history & status
- g. **ENGOT Liaison Report** (Elser)

Quality issues being addressed: clear site selection criteria, differences in surgical trials

Gynecologic Cancer Academy with aim Education of young investigators-
Translational Research subgroup formed
Publication: ROADMAP

5. New Business

- a. **Insurance/Indemnity** (Polleis/ Berger/Keller)
Survey submitted-Reply from 13 groups-results reported by Berger.
EU cannot harmonize-national matters
To be placed on Website as Resource; outstanding Groups urged to reply
- b. **Site staff-German Law** (Polleis)
Presentation of change in law regarding new definition of Site Staff-Substitute of Investigator replaces all Sub-Investigator
- c. **Trial closure/disclosure Letters (to Investigators)** (Stonebraker)
Discussion of what is requested: Trial results, How to inform patients, early closure letters-why, how to tell patients.
Examples solicited; send to Bette
- d. **Risk-Based Monitoring** (Farrelly/Negrouk)
Farrelly Report-all trials are different; no one-size-fits-all approach;
Remote monitoring plan under development
Negrouk Report on EORTC approach
- e. Translated templates – discussed. To be discussed further.

6. EU Directives update (Negrouk)

Directive well along process and when law, must be implemented (27 states),

7. AOB

- a. **Travel Policy:** Executive Board approved increase travel support up to \$2000 to 1 Harmonization rep/1 per year to better facilitate attendance at distant autumn meetings; travel booked 3 months in advance
- b. Publications-working group formed to be led by Julie Martyn/Karen Carty with Bette, Jane, Andrea, Benedicte and Laura.

8. Next meeting –May 2014 Chicago

Adjournment

5:30pm JOINT: Operations/Data Management/Stats

1. Minutes May 2013 approved

2. Website & Harmonization link Issues

Items to Post/update: Bibliography, Roster, Group Participation matrix, /Indemn. Survey results, , FDA & AMA Risk Docs, updated Agreement doc., sample Trial Closure Letter, Presentations on risk-based monitoring, EU updates.

3. Ongoing Business.

Volunteers were asked to review and recommend updates to existing tools:

- a. **Group Contacts and Summaries**-Hiltz (NCIC CTG) and Keller (NOGGO) to solicit updates from all.
- b. **Guide Book** –Aotani (JGOG) and Blattler (PMHC) to review
- c. **Mentoring** – Nepote (GEICO), Hiltz (NCIC CTG), Aotani (JGOG) & Stonebraker (GOG) – deferred.
- d. **Essential Documents** - Shevlin (ICORG) and Powell (COGi) and Berger (AGO-Au) to review

4. Quality Assurance – Auditing & Monitoring summary doc. presented. Three QA tools discussed. Comments, to Bryce (MITO), Martyn (ANZGOG), Stonebraker (GOG).

Membership Application and Membership Review forms revised - added Questions related to RT and Frequency of site auditing/monitoring.

5. New Business

- a. **Rare Tumours WG** debriefing (Paul/Votan)
 - i. Worthwhile day, Harm Operations and Stats presentation in am , and reps in all breakout working groups to work on trial development.
 - ii. Slides to be posted
 - iii. Benedicte to present in Chicago
- b. Approaches to data collection (Brady/Embleton)
On old studies
Issues regarding access to registry versus trial data discussed
REDCAP-open system, Linux computer
OPEN Clinica
Medidata Rave-possible presentation by GOG IT in Chicago
- c. Response & Progression Evaluation Issues: (Bryce/Paul)
Stats will take up question posed by Harm Ops chair regarding timing, independent versus physician determined response, and develop paper (statement) for GCIG. Survey deferred as not required by Stats.

6. GCIG Studies:

- a. Nursing – no report.
- b. Lead group issues --- none reported.

7. AOB

- a. Liaisons: At the request of Chairs of Committees and Working Groups, Exec –Board of Directors is considering having designated liaisons from both Operations and Statisticians for EACH Committee/Working Group. The delegates will be recognized liaisons, and will be expected to have pro-active roles with his/her Committee or Working Group; and, to report back to Harmonization. Bryce and Paul will discuss with members, and submit liaison names.

8. Meeting adjourned.

Respectfully submitted,

Bette Stonebraker