



GCIG-HARMONIZATION COMMITTEE

May 29th (Ops) and 30th (Joint), 2014

Double Tree Hotel, Chicago, Illinois USA

MINUTES

Present (Ops, Stats & Joint):

Members:

AGO-OVAR: Sandra Polleis, Alexander Reuss
AGO-Austria: Regina Berger
ANZGOG: Julie Martyn, Val GebSKI
BGOG: Liesbeth Lemmens, Manon Huizing
COGI: Ashley Powell
DGOG: Karen Adema-Verhoeven
EORTC: Anastassia Negrouk
GEICO: Federico Nepote
GICOM: Adriana Chavez-Blanco
GINECO: Benedicte Votan, Nathalie LeFur
GOG: Mark Brady, Bette Stonebraker
GOTIC: Sae YanagiSawa, Tetsutaro Hamano
ICORG: Anna Shevlin
JGOG: Eriko Aotani
KGOG: Byung-Ho Nam
MaNGO: Roldano Fossati
MITO: Jane Bryce
MRC/NCRI: Nikki Gower, Andrew Embleton
NCIC-CTG: Andrea Hiltz, Alison Urton
NOGGO: Maren Keller
NSGO: Tinne Kirkegaard
PMHC: Chantale Blattler
RTOG: Akila Viswanathan
SGCTG: Jim Paul, Karen Carty
SGOG: Yanfei Liu

GCIG: Monica Bacon
ENGOT liaison: Gabriele Elser
Webmaster: Dina Hess

May 29, 2014 4:00pm 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. 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 November 16, 2013 (London) as submitted (Bacon/Carty). Motion approved.

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

4. On-going business

- a. **Agreement Templates:** Update of changes presented (Carty).
Live on Website-users to provide ongoing feedback to Karen. Document to be reviewed annually (Spring Meeting).
- b. **Group Specific Appendix** (Nikki Gower for Laura Farrelly)
Survey presented- Replies from 12 Groups
Discussion ensued regarding changing title from Group Specific Appendix (GSA) to Operating Procedures (OP). Following discussion, GSA was selected as title as groups deem appropriate and needed. Comments to Laura by 9/1.
Future changes requested:
 - i) Conduct of study
 - ii) Sponsor section
 - iii) LicensingTemplate to receive annual review.
Trial Closure to be addressed
- c. **Lead Group Matrix Activity (PARTICIPATION)** (Martyn)
Document available on Website- changes to Julie for Melbourne by 9/1.
Discussion ensued regarding the Website and suggestions for changes.
Institutions to include suggestions on GCIG Evaluations
- d. **Insurance/Indemnity** (Polleis/ Berger/Keller)
Survey submitted-Reply from 13 groups- preliminary results reported by Berger in London; Survey revised to ask 7 additional questions regarding indemnification: source, type, limit, usual insurance sum, cover period, who is insured; is insurance already risk based

As of April 14th- 12 responses no essential new information

By June, outstanding Groups asked to still submit survey
- e. **Trial Closure Letters** (Stonebraker)
-examples solicited - send to Bette
- f. **Group Contacts and Summaries**

Updates needed – to Andrea Hiltz, Maren Keller
Future discussion to include insurance info

- g. Guidebook** (Tinne Kirkegaard ,Chantale Blatter)
Last version 2009
New Documents not included
Other documents updated but not updated in Guidebook (GB)
Need for GB discussed; all agreed GB was still relevant and will be updated

- h. Mentoring** (Nepote)
 - i. Need to identify new members each meeting and assign mentor:
Eriko - SGOG
Karen - BGOG
Julie – G-GOC

 - ii. Mentor Roles discussed
 - iii. Mentoring specifics- to be discussed in Melbourne
How to Lead a Trial - Andrea Hiltz
How structured, tasks of lead group - Gabriele Elser

- i. Quality Assurance** (Bryce, Stonebraker, Martyn)
Revise document based on input from Exec Committee

- j. Publication Status** (Martyn, Votan, Bryce)
Objective: Visibility, Promotion of tools, Mentorship
Final draft circulated to all prior to this meeting.
Potential Journals: Clinical Trials, Trials

- Abstracts submitted to IGCS:**
Harmonization Committee
Treatment Related Genetic Testing
Follow-up Practices During and after 1st Line Ov Ca Treatment

- k. ENGOT Liaison Report** (Elser)
Update presented - full role of ENGOT

- l. Essential Documents** (Shevlin, Powell, Berger)
 - Transfer from Votan
 - Needs updating; groups missing.

5. New Business

- a. Genetics** (LeFur, Bryce)
Counselling Survey Results presented-received 11+ replies

- b. MTA and pt. reps** (Negrouk)
will recirculate

- c. Clinical Trials Regulation** (Negrouk)
 - main positive points
 - single portal
 - all inclusive coordinated assessment

- 6. EU Directives update** (Negrouk)
- Low intervention trials- OECD Guidelines
 - Co-Sponsorship
 - Centralization of safety reporting
 - IMP for free
 - One-time consent for future research
 - Delegated acts
- Remaining issues:
- Risk adaption
 - Timelines
 - Damage Compensation
 - Implementation time
 - Legal representative for non EU sponsors
 - Submission paperwork

7. AOB

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

8. Next meeting – November 2014 Melbourne, AU

Adjournment

May 30, 2014 12:30pm JOINT: Operations/Data Management/Stats

- 1. Minutes** November 2013 approved (Carty/Kirkegaard)
- 2. Meta-analysis** (Paul) – discussion of data mining
- 3. Liaison Reports**
 - a. Executive Committee** (Bryce, Paul)
 - overview of role as liaisons
 - b. Membership** (Bryce)
 - BGOG and G-GOC approved as provisional members
 - c. Ovarian** (Carty/Embleton)
 - Presentation to Committee with little notice – well received.
 - To be posted on website.
 - d. Endometrial** (Adema/Tu)
 - No issues

- e. **Cervix** (Hiltz/Reuss)
 - Preparation for Cx Ca Brainstorming Meeting
 - Speaker -- BHNam
 - 3 breakout sessions/Ops – **A.Chavez**, E.Aotani, J.Martyn
 - 3 breakout sessions/stats - **A.Reuss**, A.Embleton, T.Hamano
- f. **TR** (LeFur/Negrrouk/Brady)
 - discussion regarding MTA
 - Operational guidelines – in draft
- g. **Rare Tumors** (Votan/Nam)
 - 500 word summary about statistical as part of RTM trials
 - Need to look at non-traditional modes
 - Need to address barriers to trials
- h. **Symptom Benefit** (Martyn/Gebbski)
 - 5 ongoing studies
- i. **Phase II** (Blattler/Paul)
 - Redesigning trials w/ accent on TR collaboration
 - Imaging timeframes
 - Protocol to collect outstanding (exceptional) responders across protocols
- j. **CCRN** (Stonebraker/Bacon)
 - Currently 4 trials: SHAPE, TACO, OUTBACK, INTERLACE
 - KGOG currently paying \$500 per patient for TACO
 - SHAPE- slow start; looking to possible add Shanghai, Prague
 - OUTBACK- halfway, 345/780; India unable to participate due to change in gov't; possibly adding Brazil and Singapore

4. Ongoing Business.

- a. Cx Ca Brainstorming as noted above (Chavez/Reuss)
- b. Approaches to data collection on international trials (Brady)
- c. Response & Progression evaluation issues (Paul/Carty/Bryce)

5. New Business

6. GCIG Studies/Updates/Issues

- a. Lead group issues --- none
- b. Nursing studies
 - MITO 12 -- closed not published
 - OV-21 – open
- c. Clinical Trial Nurses Manual (in press) ONS

7. AOB – none raised.

8. Meeting adjourned.

Respectfully submitted,

Bette Stonebraker