



GCIG-HARMONIZATION COMMITTEE

November 10th (Ops) and 11th (Joint), 2015

Jikei University, Tokyo Japan

Chair: Bette Stonebraker

Co-Chair: Benedicte Votan

Past Chair: Jane Bryce

MINUTES

Present (Ops, Stats & Joint):

Members:

ACRIN: Chaan Ng [CN]
AGO-OVAR: Alexander Reuss [AR], Gabriele Elser [GE](& ENGOT liaison)
AGO-Austria: Regina Berger [RB] (guest: Paul Speiser)
ANZGOG: (guests: Peter Sykes, Alison Davis)
BGOG: absent
COGI: (guest: Wendy Fantl)
DGOG: absent
EORTC-GCG: absent
GEICO: absent
GICOM: Adriana Chavez-Blanco [AC]
GINECO: Benedicte Votan [BV], Xavier Paoletti [XP]
GOG: Bette Stonebraker [BS]
GOTIC: Eriko Aotani [EA], Tetsutaro Hamano [TH]
G-GOC: absent
ICORG: absent
ISGO: absent
JGOG: Ayumi Mukayama [AM], Yuki Inokuchi [YI]
KGOG: Byung-Ho Nam [BHN], JongSoon Kim [JSK], Bomi Choi [BC]
MaNGO: absent
MITO: Jane Bryce [JB]
MRC/NCRI: Laura Farrelly [LF]
NCIC-CTG: Dongsheng Tu [DT]
NOGGO: Maren Keller [MK]
NSGO: absent
PMHC: Chantale Blattler [CB]
RTOG: (guest: Bill Small, GCIG Chair)
SGCTG: absent
SGOG: absent
GCIG: Monica Bacon [mB], Katherine Bennett [KB]
Webmaster: Nicole Cummings [NC]

Nov 10th, 2015 9am OPERATIONS/DATA MANAGEMENT

1. Welcome and Introduction:

- a. BS welcomed members and the new members and guests : Ayumi Mukayama and Yuki Inokuchi from JGOG and Peter Sykes and Alison Davis (here as guests) from ANZGOG and Wendi Fantl from COGI (here as guest)
- b. No participants declared any Conflict of Interest

2. Approval of Minutes

No correction on the Chicago 2015 minutes which are approved

Motion: Jane Bryce Seconded: Laura Farelly - All in favour

3. Minuter: BV minuter for this meeting

4. New business

a) Budgeting in Intergroup trials (LF and AC)

A presentation on how to budget a trial has been made by LF; AC presented an example of template (excell sheet) for budgeting a trial. It has been agreed that each group which has experience in budgeting a trial would send their template to AC who will try to create a template + guidance :

⇒ Action for next meeting in Chicago : AC to create a template + guidance and to present at next meeting

RB will present at the next meeting in Chicago the presentation from the last ENGOT meeting on budgeting a trial :

⇒ Action for next meeting RB to present the experience of AGO-Austria in how to budget a trial

b) Communication in Intergroup trials

A presentation on communication in Intergroup trials has been made by BV. It has been agreed that it would be interesting to have a GCIG template for communication plan.

⇒ Action for next meeting : LF will send some examples of communication plan and the communication working group (Natalie le Fur [NF], Elke Neven [EN]) will create a template based on these examples. Template to be presented at the next meeting in Chicago

5. On-going business

- a. **Group Specific Appendix** (LF)
GSA now available on website.

It has been reminded that each harm person responsible for a document (GSA, IA, guide book...) needs to verify that the current version of the document is available on the website

- b. Intergroup Agreement** (BV for NF and Karen Carty [KC])
 Slide presentation made by BV. The current version of IA must be corrected :
- Paragraph 9.1 and 9.1 should be modified and the new wording proposed by BV is accepted
 - Paragraph 9.3 should be modified but new wording has to be proposed
 - Paragraph about insurance : should be modified because it is unclear
- ⇒ **Action before next meeting** : the working group has to propose new wording about insurance and has to work up a paragraph on insurance; new version of IA should be circulated so that it can be presented and validated at the next meeting in Chicago
- c. Lead Group Matrix Activity (PARTICIPATION)** (Julie Martyn [JM])
 No update.
- d. Insurance/Indemnity** (RB/MK/ Sandra Polleis[SP])
 No update – Still some groups which haven't answered the survey : BGOG, COGi, G-GOC, KGOG, RTOG and SGOG.
 ⇒ **Action** : these listed groups to complete the survey
- e. Trial Closure Letters** (BS)
 BS presented an example of closure letter – NO action required
- f. Group Contacts and Summaries** (MK)
 Still outstanding groups to reply: MaNGO
 ⇒ **Action : MANGO to complete its section +++**
- g. Guidebook** (CB)
 CB presented the update of guide book : some new sections added
- h. Welcome-Mentoring** (BS for Frederico Nepote [FN])
 Mentor to be chosen for BGOG :
 ⇒ **Action : Bette will assign a mentor**
 ENGOT's revisions/updates to be shared.
- i. Essential documents** (RB/ Beatta Sapeto [BSR])
 Update to be done at the next Chicago meeting
- j. ENGOT Liaison Report** (GE)
 Cf slide presented by GE below :
- Elections of Clinical & Administrative Vice- Chair 2015-2016 (ENGOT Vice Chair starting Fall 2016-17 & 2019-20 and ENGOT Chair 2017-2019) Sandro Pignata, MITO Italy & Regina Berger, AGO Austria
 - Network and GCA meetings in October 2015 (Translational ResearchDevelopment of Biobank, Phase II Network)
 - e-Learning module ongoing (see ESGO webpage)

- EU current status CTR (Clinical Trials Regulation) not before 28/05/2016

- Admin tasks :
 - Welcome package (FN) to be harmonized with GCIG welcome package;
 - Risk based monitoring – definition of RBM and its use in clinical trials;
 - Networking Monitoring – new task to be followed-up ;
 - Budgeting of a clinical trial – first discussion. Ongoing task

6. New Business for next meeting

- Budgeting and communication to continue

⇒ **Action for everybody** : Everybody is asked to send idea/subjects to be discussed at the next Chicago meeting to BS

7. Next meeting – June 2015- Chicago

Adjourn

Nov 11, 2015 8:00 am JOINT: Operations/Data Management/Stats

1. **Introductions-** (BS & BHN)
2. **Minuter** - (BV)
3. **Conflict of Interest** –None to report
4. **Minutes** Chicago June 2015 minutes- approved as filed
5. **Liaison Reports**
 - a. **Executive Board of Directors** (JB, BS, BHN)
 - no report
 - b. **Ovarian** (KC/Andrew Embleton [AE] -- absent)
 - new trial concepts presented over the lunch break.
 - c. **Endometrial** (DT) (Karen Adema [KA] absent)
 - many trials presented, difficult to follow
 - d. **Cervix** (AR) (Andrea Hiltz [AH] absent)
 - big issue = no money !
 - f. **Trans Research** (BV for NF/Anastassia Negrouk [AN]/Mark Brady [MB] absent)
 - Meeting not yet held - Brainstorming session on TR in Lisbon,
 - Harmonization representatives to attend
 - g. **Rare Tumors** (BV/BHN)
 - no items to report
 - h. **Symptom Benefit** (JB for JM absent)

Discussion about QoI with missing data, how to deal with them + how to manage this issue in the future with the risk based monitoring ?
Guest to be invited for presentation of new CTCAE/PRO in Chicago during harmonization session. Joint session with SB Committee.

- i. **Phase II (CB)**(Jim Paul [JP] absent)
Deferred – no report as meeting held concurrent with Harm Meeting; subsequent report was that a lengthy discussion took place regarding logistical and data ownership issues of proposed Umbrella trial –
⇒ to be discussed at joint Harm/Ops meeting in Chicago
- j. **CCRN (BS/mB)**
Education symposium planned for January in Bangkok.

8 Ongoing Business.

- a. **Q.A. (JB, BS)**
New working group. Request for interested Harm/Ops members to participate. Each GCIG group will be asked to provide a rep.

- b. **Harmonization Manuscripts**

- 1) Harmonization committee : many comments received from the review by Clinical Trials journal : the paper should be rewritten and resubmitted before 1st December : **action JB, BV, BS.**
- 2) BRCA testing survey paper combined with second GCIG survey; accepted in Gynecologic Oncology
- 3) Ovarian cancer assessments survey : in draft, to be submitted

9 New Business

Megadatabase new working group : it has been decided that EA w be the operational harm liaison; each GCIG group will be asked to provide a rep.

10 GCIG Studies/Updates/Issues

No new updates

- 11 **AOB** – subjects to be discussed at the next Chicago meeting : Umbrella trials and issues linked to this type of trial (regulatory issues, operational issues, stat issues...etc).

Reminder: there are bound to be conflicts. Harmonization reps (liaisons) are reminded that their priority is to attend Harmonization meetings (especially when receiving GCIG travel support).

12 Meeting adjourned.

Respectfully submitted,

Bénédicte Votan, Harmonization Ops co-Chair

