



GCIG-HARMONIZATION COMMITTEE

June 2nd (Ops) and 3rd (Joint), 2016

Double Tree Hotel, Chicago, IL, USA

Chair: Bette Stonebraker

Co-Chair: Benedicte Votan

Past Chair: Jane Bryce

MINUTES

Present (Ops, Stats & Joint):

ACRIN: absent
AGO-OVAR: Alexander Reuss [AR], Sandra Polleis [SP]
AGO-Austria: Regina Berger [RB]
ANZGOG: Val GebSKI [VG]
BGOG: absent
COGI: PJ Chang [PC]
DGOG: Karen Verhoeven [KAV]
EORTC-GCG: Anastassia Negrouk [AN]
GEICO: Federico Nepote [FN], Ana Levin [AL]
GICOM: Adriana Chavez-Blanco [AC]
GINECO: Benedicte Votan [BV], Nathalie LeFur [NL-F], X. Paoletti [XP]
GOG: Bette Stonebraker [BS], Mark Brady [MB]
GOTIC: (guest: Keiichi Fujiwara)
G-GOC: Susan Pilat [SP]
ICORG: Beatta Sapetto-Rebow [BS-R]
ISGO: Leora McCullough [LM]
JGOG: N. Yanaihara [NY] (guest: Nao Suzuki)
KGOG: Byung-Ho Nam [BHN]
MaNGO: Roldano Fossati [RF]
MITO: Jane Bryce [JB]
MRC/NCRI: Laura Farrelly [LF], Andrew Embleton [AE]
(NCIC) CCTG: absent
NOGGO: Maren Keller [MK]
NSGO: Louisa Boufercha [LB]
PMHC: Chantale Blattler [CB]
RTOG: (guest: Bill Small, GCIG Chair)
SGCTG: Karen Carty [KC]
SGOG: absent
NCI US: absent
GCIG: Monica Bacon [mB], Katherine Bennett [KB]
Webmaster: Nicole Cummings [NC]

June 2nd 4.30pm OPERATIONS/DATA MANAGEMENT

1. Welcome and Introduction:

- a. BS welcomed members and the new members and guests : Leora McCullough, ISGO; Ana Levin, GEICO; Louisa Boufercha, NSGO; and N Yanaihara, JGOG)
- b. No participants declared any Conflict of Interest

2. Approval of Minutes

No correction on the Tokyo 2015 minutes which are approved

Motion: Jane Bryce Second: Laura Farrelly - All in favour

3. Minuter: BV minuter for this meeting

4. On-going business

a. Budgeting in Intergroup Trials

(Farrelly, Chavez, Berger)

A.Chavez presented a way of budgeting a trial without forgetting any task and she presented a complete template.

- **Action:** the WG should discuss again within the group and then send a template to each of the group. Each group should give feedback on this template. To be discussed again at the next meeting and to include the template in the Harmonization guidebook once adopted

b. Communication in Intergroup trials

Presentation of the first draft for communication plan in an intergroup trial.

The next step is to validate this draft by the WG, then to make this draft circulate in order to definitely adopt the template at the next GCIG meeting in Lisbon

- **Action :** validation of the draft by the WG (Nathalie LeFur, Laura Farrelly, Anastassia Negrouk) , then circulation in September in order to be adopted in Lisbon in October

c. Intergroup Agreement

Updates and new wording have been presented. The goal is to have the final updated version by End of June in order to have the final version in the website for this summer.

- **Action:** Karen to update and send the final version by end of June. (Post-meeting note : done)

It has been discussed the interest of having someone in this WG coming outside Europe as today only representatives of Europe are present in this WG.

- **Post-Meeting note:** Bette is interested in being included in this WG. **Action BV to inform the WG.**

d. Lead group matrix activity

Following Julie's departure, Karen Verhoeven from DGOG agreed to be in charge of this group. It has been agreed to have this document updated once a year. Some people would like to have the number of patients per year and per group on this document : → **Karen to add this information in the document**

e. Insurance/Indemnity (RB/MK/ Sandra Polleis[SP])

Still some groups which haven't answered the survey: BGOG, KGOG, SGOG.

⇒ **Action** : these listed groups to complete the survey

A publication is currently in preparation and the first draft should be ready very soon

f. Group Contacts and Summaries (MK)

Only ISGO group is now missing (but new group)

- **Action** : ISGO group to complete this document

g. Guidebook (CB)

The final version should now be on the website

- **Action** : Chantale to put the final version of guidebook on the website

h. Welcome-Mentoring (Frederico Nepote [FN])

The welcome package should continue to be reviewed/update on an ongoing basis and the updated package should be on the website along with the updated group mentoring assignments

- **Action** : FN to update and put the welcome package on website and to share ENGOT's revisions/updates

i. Essential documents (RB/ Beata Sapetto-Rebow [BSR])

4 groups are still missing.

It has been agreed that the WG should continue to work in order to define the parameters of what constitutes “Essential” as requirements vary so much from group to group

- **Action** : WG to define these parameters and to present at the next meeting

j. ENGOT Liaison Report (BV for GE)

Risk based monitoring – example with Paola trial

Networking Monitoring – new task to be followed-up and further discussed in Lisbon in collaboration with the QA WG

Budgeting of a clinical trial –

5. Next meeting – October 2016 Lisbon

Adjourn

June 3rd 3.30pm JOINT: Operations/Data Management/Stats

- 1. Introductions-** (BS & BHN)
- 2. Minuter -** (BV)
- 3. Conflict of Interest** –None to report
- 4. Minutes** Tokyo November 2015 minutes- (motion by Karen second Jane) - approved
- 5. Website and harmonization page** (Cummings)

It has been reminded that each responsible of WG should check that final current version of document is available on the website

It has been discussed the need to have a private page for harmonization with password

6. Liaison Reports

- a. Executive Board of Directors** (JB, BS, BHN)
-no report
- b. Ovarian** (KC/Andrew Embleton [AE])
-nothing to report.
- c. Endometrial** (DT) (Karen Verhoeven [KV])
-nothing to report

d. Cervix (AR) (Andrea Hiltz [AH])
-nothing to report

e. Trans Research (LeFur)

Nothing to report

f. Rare Tumors (BV/BHN)
-no items to report

g. Symptom Benefit (Polleis)

Discussion ensued concerning the PRO_CTCAE previously presented. No action taken at this time.

i. Phase II (CB)(Jim Paul)

CB reported on the Working Group's discussion of the Study Process and the need for Validation

Byung Ho Nam presented an overview of the logistical issues of platform trials. Building platform trials based on biomarker status allows work on multiple drugs in one trial. Example of Basket vs Umbrella trial concept was presented.

j. CCRN (BS/mB)

Funding continues to be an issue;
Education essential to Promote available trials;
OUTBACK accruing ahead of schedule;

8 Ongoing Business.

a. Q.A. – Initial meeting of WG; GCP, Badging a trial and creation of a monitoring, auditing, network panel discussed;

b. Harmonization Manuscripts

1) Outside advice is still being sought regarding possible amendments and whether to resubmit or submit to another journal

9 New Business

10 **AOB**

11 **Meeting adjourned.**

Respectfully submitted,

Bénédicte Votan, Harmonization Ops co-Chair