



GCIG-HARMONIZATION COMMITTEE

October 26th (Ops) and 28th (Joint), 2016

Double Tree Fontana Hotel, Lisbon, Portugal

Chair: Bette Stonebraker Co-Chair: Benedicte Votan Past Chair: Jane Bryce

MINUTES

Present (Ops, Stats & Joint):

ACRIN:
AGO-OVAR: Alexander Reuss [AR], Sandra Polleis (SP)
AGO-Austria: Regina Berger [RB]
ANZGOG: guests: Alison Brand
BGOG: L Hombrouck, E Peeraer
COGI: PJ Chang
DGOG: K Verhoeven
EORTC-GCG: A.Negrout (AN)
GEICO: A.Levin (AL)
GICOM: Adriana Chavez-Blanco [AC]
GINECO: Benedicte Votan [BV] – Nathalie Le Fur (NLF)
GOG: Bette Stonebraker [BS]
GOTIC: Guest: K.Fujiwara
G-GOC: absent
ICORG : B Sapetto-Rebow
ISGO: absent
JGOG: absent
KGOG: Byung-Ho Nam [BHN]
MaNGO: absent
MITO: Jane Bryce [JB]
MRC/NCRI: Laura Farrelly [LF]
NCIC-CTG: absent
NOGGO: Maren Keller [MK]
NSGO: E Roennengart
PMHC: Chantale Blattler [CB]
RTOG:
SGOG: absent
GCIG: Monica Bacon [mB], Katherine Bennett [KB]
Webmaster: absent

October 26th 4.30pm OPERATIONS/DATA MANAGEMENT

1. Welcome and Introduction:

The meeting was opened with a tribute to Eriko Aotani.

- a. BS welcomed members and the new members and guests : Leen and Eve from BGOG, Eva from NSGO and guests : Keiichi Fujiwara, Ros Glaspool and Alison Brand
- b. No participants declared any Conflict of Interest

2. Approval of Minutes

No correction on the Chicago June 2016 minutes which are approved

Motion: Jane Bryce Seconded: Nathalie Le Fur - All in favour

3. Minuter: BV minuter for this meeting

4. New Business

PRO-CTCAE working group

Everybody agreed that there were no need to create a new WG for the moment as this topic could be discussed during the harmonization meeting

Mega-database presentation

R.Glaspool (RG) made a presentation on the mega-database WG and presented the aim of the WG :

- To perform individual patient level meta-analyses in order to address questions that cannot be answered by individual trials.
- To identify key questions and develop projects to address them
- To create an infrastructure that will facilitate meta-analysis projects between GCIG groups.

RG presented a draft of a data-sharing template agreement : the aim of this template would be to develop an agreement which could be accepted by all groups.

RG asked harm people to constitute a small group in order to validate the terms of the agreement.

→ **Action : ask for some volunteers for this WG**

5. On-going business

BS asked all groups to have a look of all docs in the website and to come back to Cathy to confirm that this is the final version

→ **Action (all) : to confirm that version of docs in website is the final one**

a. Budgeting in Intergroup Trials (Farely, Chavez, Berger)

A.Chavez presented the current version of template that she sent to the groups for discussion : she received the answer from 7 groups. The feedback given by the groups was that it was a useful tool but it was noted that there were some differences between countries, regions and groups in budgeting studies. This tool can be an alternative tool to aid in the process of budgeting but it has been agreed that a check list would be better

⇒ **Action** : the WG will work on a checklist and will make circulate this checklist to the harm committee with ultimate goal to include this checklist in the Guidebook. This checklist will be presented at Chicago

b. Communication in Intergroup trials

Presentation of the second draft (not totally final yet) for communication plan in an Intergroup trial. Some items needs to be discussed and validated.

⇒ **Action (NLF)** : Final draft should be in circulation and validated in December 2016 in order to post the document on website before the Chicago meeting. Once posted, people are encouraged to test it and give feedback at Chicago meeting

c. Intergroup Agreement

Final version dated Jul2016 posted on website – to be used

d. Lead group matrix activity

Some new information have been added (number of patients/year/group, protocol accrual per group, tumor type)

⇒ **Action (KA)** : to be distributed to the groups for last comments

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

Final draft of publication to be circulated before the end of the year for comments

⇒ **Action** : SP to send the final draft for comments

f. Group Contacts and Summaries (MK)

Each group should check the section monitoring and audit and update it if necessary

⇒ **Action (each group)** : to check and complete section monitoring

g. Guidebook (CB)

The final version is now be on the website with new section on monitoring and site selection. If someone would like to add something, he should inform Chantale.

h. Welcome-Mentoring

Many new people in the harm committee and this Welcome Package (WP) is very useful.

The updated mentoring assignments is an ongoing process : each new group (new person) should have a mentor and the mentor should tell the new person where to find the WP which is now posted on the website.

It has been decided to create a checklist to aid the mentoring process and to hold a mentoring session for new people just prior to June Harm meeting.

⇒ **Action** : Jane, Bette and Bénédicte to create the checklist and Bette to discuss and organize with Monica the mentoring session

Mentoring assignments :

Leora → Bénédicte

Eva → Jane

Leen → Karen

Ana → Adriana

Susan → Chantale

i. Essential documents (RB/ Beatta Sapeto [BSR])

The essential documents checklist has been presented and is now ready for posting pending updates by a couple of groups (RTOG,SGOG)

Action : to put this version on website and to give feedback if some groups are using it

j. ENGOT Liaison Report (RB for GE)

Regina presented the ENGOT report of the adm meeting held at the last ENGOT meeting in October.

As many topics are very similar to the harmonization documents, it is very important not to duplicate things.

Monica (GCIG liaison for Engot) and Gabriele (ENGOT liaison for GCIG) have to work together to list all documents in both groups.

k. Other new business

It has been agreed that a Rules and Responsibilities document for Harmonization Rep and liaison should be created

⇒ **Action** : Bette and Bénédicte to work on this document

6. Next meeting – June 2017 in Chicago

Adjourn

October 28th JOINT: Operations/Data Management/Stats

1. **Introductions-** (BS & BHN)
2. **Minuter -** (BV)
3. **Conflict of Interest** –None to report
4. **Minutes** Chicago June 2016 minutes- Motion: Laura Farrelly Second: Nathalie LeFur- approved as submitted
5. **Website and harmonization page** (Benett)

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

6. **Liaison Reports**

- a. **Executive Board of Directors** (JB, BS, BHN)
-no report

- b. **Ovarian** (Levin)
-nothing to report.

- c. **Endometrial** (Verhoeven)
-nothing to report

- d. **Cervix** (BS)
-nothing to report

- e. **Trans Research** (Lefur)

Report from brainstorming: a pathology manual should be created

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

- g. **Symptom Benefit** (Polleis)

- PRO-CTCAE currently available in English and Spanish and on the way for German, Swedish, Danish, Chinese, Japanese, Korean, Italian
Missing: French, Russian, Hebraic, Dutch, Norwegian, Finnish

- i. **Phase II** (CB)(Jim Paul)

Update on the Umbrella trials which are moving well

- j. **CCRN** (BS/mB)
Nothing to report

k. Mega-database WG

Group is now renamed Meta analyses group

8 Ongoing Business.

- a. Q.A.** small working groups to work on minimum QA standard for GCIG, minimum standard for centralized monitoring and minimum standard for vendor assessment – Surveys will be sent to groups
- b. Harmonization Manuscripts : has been sent to G.Stuart for review**

9 New Business

10 AOB

11 Meeting adjourned.

Respectfully submitted,

Bénédicte Votan, Harmonization Ops co-Chair