



GCIG-HARMONIZATION COMMITTEE

Thursday, June 1, 2017, 4:30pm – 6:00pm

DoubleTree Hotel, Chicago, IL, USA

I

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:

BGOG: L Hombrouck

COGI: Pei-Jen Chang

DGOG: K Verhoeven

EORTC-GCG:

GEICO: A. Levin (AL)

GICOM: Adriana Chavez-Blanco [AC]

GINECO: Benedicte Votan [BV] – Nathalie Le Fur (NLF) – Xavier Paoletti

GOG: Bette Stonebraker [BS] – Bill Brady

GOTIC: Yusuke Kajimoto

G-GOC:

ICORG : Beata Sapetto-Rebow

ISGO: absent

JGOG:

KGOG:

MaNGO: Elena Biagioli and Roldano Fossati

MITO: Jane Bryce [JB]

MRC/NCRI: Laura Farelly

NCIC-CTG:

NOGGO: Maren Keller [MK]

NSGO:

PMHC: Chantale Blattler [CB]

RTOG:

SGOG:

SGCTG: Karen Carty – Jim Paul

GCIG: Katherine Bennett [KB]

Webmaster: Matthew Beyers

1. Welcome and Introduction:

- a. BS welcomed members and the new members : Yusuke from GOTIC and Elena from Mango
- b. No participants declared any Conflict of Interest

2. Approval of Minutes

No correction on the Lisbon November 2016 minutes which are approved

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

3. Minuter: BV minuter for this meeting

4. Addition to agenda : Principles of independence document : Bette presented the document . This document should circulate and harmonization people should comment on it if needed

⇒ Action Bette for circulation

5. On-going business

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

A.Chavez presented the checklist for budgeting. The objective is to add this checklist to the guidebook

⇒ Action (Adriana) : Adriana should make circulate this checklist and if comments harmonization people should send their comments to Adriana

b. Communication in Intergroup trials

The document has been sent to everybody for comments 2 weeks before the meeting and is now final: it will be posted on the website and everybody will be able to use it

⇒ Action (NLF) : Final version to send to Matthew/Kathy in order to be posted on website

c. Intergroup Agreement

Final version dated Jul2016 posted on website – If someone uses it, please send the comments to Nathalie/Karen

d. Lead group matrix activity

The document lead group matrix will be combined with the clinical trial list document as both documents have same objectives

⇒ **Action (KA) : to combine both documents**

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

Sandra presented the final version of manuscript. The objective is to submit to International Journal of Gyn Cancer very soon (June/July)

Sandra informed the committee that a new survey about cost of insurance/patient and other things will be sent to the harm people.

⇒ **Action : SP to submit manuscript and to prepare and send the new survey**

f. Group Contacts and Summaries (MK)

Nothing new.

g. Guidebook (CB)

Nothing new

h. Welcome-Mentoring

Bette informed the committee that a mentoring session (overview orientation) was held just before the harmonization meeting for new members Yusuke and Elena. This process will be expanded in the future. These 2 new members were assigned a mentor (Bénédicte for Yusuke and Jane for Elena)
Bette informed the committee that the welcome package is posted on website

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

The essential documents checklist is now posted on website.

Action: to look at this checklist and to give feedback

j. ENGOT Liaison Report (BV for GE)

Bénédicte presented the ENGOT report of the adm meeting held at the last ENGOT meeting in March.

k. Other new business : Rules and Responsibilities (BS)

Bette presented a document for R&R for harmonization representatives and for harm liaison: what are the expectations and responsibilities to be a harmonization representative or harm liaison?

⇒ **Action : Bette to make circulate this document and if no comment to add this document to the welcome package**

6. Next meeting – November 2nd in Vienna

Adjourn

June 2, 2017 JOINT: Operations/Data Management/Stats

1. **Introductions-** (BS & BHN)
2. **New members : Bill Brady from GOG**
3. **Minuter -** (BV)
4. **Conflict of Interest** –None to report
5. **Minutes** Lisbon Oct 2016 minutes- approved as submitted
6. **Website and harmonization page** (M.Beyers)

Matthew presented the GCIG website and informed that the site comes as number 1 in the list. He informed the assembly that the roster will change: now collection of emails, job titles, credentials...

He presented the harmonization page with all tools.

He asked for volunteers to have a look on website: Karen from DGOG, Kathy, Ana from GEICO and Matt will form a group.

7. 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, Brady)
Nothing to report
NB: the liaisons people should be replaced
- f. **Rare Tumors** (Farely/BHN)
-No report – meeting at same time

g. Symptom Benefit (Polleis)

- PRO-CTCAE currently available in different languages or in development
The MOST questionnaire should be on the home page of website. Advertisement should be done –
Question: shall we ask Industry partners to pay?

i. Phase II (CB)(Jim Paul)

Update on the Umbrella trials which are moving well: the harmonization people should follow carefully this trial

j. CCRN (BS/mB)

Nothing to report

k. QA working group

Jane informed harm people about the QA brainstorming in Vienna. This brainstorming should last ½ day just before the GCIG meeting
2 People/group should attend including a clinician.

l. Meta analyses WG

BV informed the harm committee that the data sharing agreement used to start with the groups having already accepted is the one from GINECO. It is agreed that this could be considered as the first GCIG template. This template will of course evolve but everybody agreed that this is a good start.

8 Ongoing Business.

- a. Harmonization Manuscripts:** it was discussed about the publication status and what to do now; some volunteers are needed to take over as Jane can not be involved anymore.

Action: Ask for volunteers to take over

9 New Business : Measuring “financial toxicity” (FT) :

→ Action Jane to provide some information to the harm committee at next meeting

10 **AOB**

11 **Meeting adjourned.**

Respectfully submitted,

Bénédicte Votan, Harmonization Ops co-Chair