



## **GCIG-HARMONIZATION COMMITTEE**

**May 28<sup>th</sup> (Ops) and 29th (Joint), 2015**

**DoubleTree Hotel, Chicago**

### **MINUTES**

#### **Present (Ops, Stats & Joint):**

##### **Members:**

ACRIN: absent  
AGO-OVAR: Alexander Reuss, Sandra Polleis  
AGO-Austria: Regina Berger  
ANZGOG: Julie Martyn, Val GebSKI  
BGOG: Liesbeth Lemmens  
COGI: Ashley Powell, (guest: Nadeem Aub-Rustum)  
DGOG: Karen Verhoeven-Edema (guest: Ana Reyner)  
EORTC-GCG: Anastassia Negrouk  
GEICO: Federico Nepote  
GICOM: Adriana Chavez-Blanco (guest: Luis F. Onate-Ocana)  
GINECO: Benedicte Votan, Nathalie LeFur (guest: Florence Joly)  
GOG: Bette Stonebraker, Mark Brady  
GOTIC: Eriko Aotani (guest: Keiichi Fujiwara)  
G-GOC: Susan Pilat (guest: Audrey Tsunoda)  
ICORG: Beata Sapetto-Rebow  
JGOG: Masahiko Wantabe, Takaaki Takenaga  
KGOG: Byung-Ho Nam, JongSoon Kim, Bom Choi, Suk-Joon Chang  
MaNGO: (guest: Ornella Nicoletto)  
MITO: Jane Bryce ( guest: Domenica Lorusso)  
MRC/NCRI: Laura Farrelly, Andrew Embleton  
NCIC-CTG: Dongshen Tu (guest: Hal Hirte)  
NOGGO: absent  
NSGO: Tinne Kirkegaard  
PMHC: Chantale Blattler  
RTOG: (guest: Akila Viswanathan)  
SGCTG: Jim Paul  
SGOG: Xin Liu, Chen Xiaojuu  
GCIG: Monica Bacon  
ENGOT liaison: Gabriele Elser  
Webmaster: Nicole Cummings

Guests: Bill Small, GCIG Chair  
Jan Vermorken, GCIG founding Director  
Paul Mitchell, Lung Group  
Sabine Corachan, BIG  
Catherine Mwaba, Zambia  
Kathy Look, Genentech-Roche  
Hiroki Kato - Zeria

**May 28, 2015 4:00pm OPERATIONS/DATA MANAGEMENT**

**1. Welcome and Introduction:**

- a. Jane Bryce (JB) welcomed members and Guests, Sabene Corachan from BIG, and Dr. Paul Mitchell of the Lung Cancer Intergroup (to be formally named)
- b. No participants declared any Conflict of Interest

**2. Approval of Minutes**

Correction was made to the Minutes of meeting November 5th, 2014 (Melbourne) to state that ICON 8 has completed accrual. Motion and second to approve as amended (Farrelly/LeFur). Motion approved.

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

**4. On-going business**

**a. Group Specific Appendix** (Laura Farrelly)

Final changes sent in March for upload to the GCIG Website- posting still needed to be done.

**b. Intergroup Agreement** (Nathalie LeFur for Karen Carty)

Slide presentation of Version 2 (20/10/2013); discussion ensued primarily around primary responsibility and insurance obligation; clarification of lead group vs. participating group; removed indemnification.

**c. Lead Group Matrix Activity (PARTICIPATION)** (Julie Martyn)

Presented by Julie; all felt useful for obtaining trial information such as status, accrual, etc. Discussion ensued regarding ways in which document could be utilized by Groups.

**d. Insurance/Indemnity** (Sandra Polleis/ Regina Berger/Maren Keller)

Slide presentation -6 Groups still missing from Survey results

Survey results:

- Regulated by laws in each country
- Limitations of liability different in each country
- No changes in results form 2013
- If subject has health insurance special requirements in each country
- Liability insurance – site/investigator required for all but one country
- Travel insurance required in most countries
- Trial insurance required for all countries
- Indemnification limits per patient, per trial, per year

**e. Trial Closure Letters** (Bette Stonebraker)

Deferred to November 2015 due to time restraints

- f. **Group Contacts and Summaries** (Andrea Hiltz, Maren Keller)  
Still Outstanding Groups to reply: ACRIN, DGOG, GOTIC, MaNGO  
Submit info to Hiltz and Keller
- g. **Guidebook** (Tinne Kirkegaard ,Chantale Blatter)  
Distributed 05/27/15 via email for comments
- h. **Mentoring** (Federico Nepote)  
Slides presented; discussion to create tutorial; present mentoring topic every meeting
- i. **Quality Assurance** (Jane Bryce, Bette Stonebraker, Julie Martyn)  
Deferred to Joint meeting 05/29
- j. **Publication Status** (Julie Martyn, Benedicte Votan, Jane Bryce)

Abstracts to become publications:

- Harmonization Committee- Julie - in Draft
- Treatment Related Genetic Testing-status unknown
- Follow-up Practices During and after 1<sup>st</sup> Line Ov Ca Treatment-Karen  
Working on draft

- k. **ENGOT Liaison Report** (Gabriele Elser)
  - Implementation of new regulation
  - High to do intergroup trials
  - Federico to speak to mentoring at ENGOT
  - Risk-based monitoring
  - ENGAGE advocacy group of ENGOT
  - ENGOT Group support ESGO e-learning programming next meeting
- l. **BIG Presentation** by Sibene Corachan
  - Non-profit network of academic breast cancer groups
  - 55 members
  - >30 clinical trials
  - Brussels based HQ; member group's data centers manage data
  - BIG Umbrella 3 trial models: Supporter, Lead; Co-lead
  - Leader of specific tasks "To determine the degree of harmonization, Standardization and integration that is desired and feasible"
  - Group interest/site feasibility
  - Site feasibility tools
  - Master group agreement
  - Master Confidential Disclosure Agreements (CDAs)
  - 2015 Partnership Working Principals
    - Co-Lead partnership models
    - Budgeting co-lead partners
    - Improve Site contracting
    - Principals for site budgets
  - Operational Working Group Harmonization
    - OWG initial reaction that this was difficult due to specific SOPs in

Each Group

**CONCLUSION: “No clarity for the Groups on what can be harmonized.”**

**5. New Business**

- a. Budgeting of trials (Martyn, Chavez, Farrelly)  
Survey of groups’ budget practices/needs conducted, results and further budget discussion deferred to 11/2015
- b. Managing Communications (LeFur)  
Deferred to 11/2015

**6. EU Directives update** (deferred)

**7. AOB**

Deferred

**8. Next meeting – November 2015- Tokyo, Japan**

**Adjournment**

**May 29, 2015 8:00 am JOINT: Operations/Data Management/Stats**

- 1. **Introductions-** (Jane Bryce & Byung-Ho Nam)
- 2. **Minuter** - (Bette Stonebraker)
- 3. **Conflict of Interest** –None to report
- 4. **Minutes** November 2014- approved as filed
- 5. **New Business**
  - a. **Risk Based Monitoring Slide Presentation** (Benedicte Votan)  
Why developed- Limitations of on-site monitoring is inadequate  
Electronic data systems offer opportunities  
How to use-focus on most critical; define most critical; adjust strategy; total different approach  
FDA believes that targeted risk-based approaches that focus on most critical elements will result in more effective monitoring (PAOLA-1)  
Discussion of source docs into English-No document for remote monitoring regarding language  
Assess -have monitoring plan (revisit)

**b. Trial Design with Biomarkers Presentation** (Byung Ho)

How do we incorporate:  
Biomarker definition  
Prognostic Biomarker  
Predictive Biomarker  
Biomarkers in Phase I, II  
BATTLE trial – lesson learned – doable  
Randomized Phase III :  
Biomarker strategy designs  
Biomarker enrichment designs

**6. Website Report** (Nicole Cummings)

New Website in 90 days  
New look, new feel, new enhanced features  
Portions to be password protected

**7. Liaison Reports**

**a. Executive Committee** (Jane Bryce, Byung-Ho Nam)

-no report

**b. Membership** (Jane Bryce)

-no items

**c. Ovarian** (Karen Carty/Andrew Embleton)

-no items

**d. Endometrial** (Karen Adema/DongSheng Tu)

-indemnity issues- need to delegate insurance issues to co-ordinating center

**e. Cervix** (Andrea Hiltz/Alexander Reuss)

-deferred—meeting not yet held

**f. TR** (Nathalie LeFur/Anastassia Negrouk/Mark Brady)

GCIG Material Transfer & Service Agreement:

Contract with Institution, Bank, Sponsor, Provider (person providing samples - pathologist, lab)

Sponsor –financial responsibility

Custodian – legal entity responsible for satisfying the material coordination

IP (Intellectual Property) doesn't actually change hands

Publication Guidelines- future directions- creation of GCIG Publication

Guidelines for TR; define validated laboratory

Discussion ensued regarding patient consent

Brainstorming session on TR in Lisbon

**g. Rare Tumors** (Benedicte Votan/Byung-Ho Nam)

-discussion regarding no design

**h. Symptom Benefit** (Julie Martyn)

On-line questionnaire for endometrium- will present next time

**i. Phase II** (Chantale Blattler/Jim Paul)

Deferred -meeting not yet held

**j. CCRN** (Bette Stonebraker/Monica Bacon)

TACO future uncertain- Korea pulled funding

**8. Ongoing Business.**

**a. Q.A.**

A QA committee formed at Strategic Planning will continue work to define a QA plan/policy. Request for interested Harm/Ops members to participate

**b. Harmonization Manuscripts**

- 1) Update of Ops papers- Julie
- 2) BRCA testing survey paper combined with second GCIG survey; being submitted – Jane

**9. New Business**

Strategic Planning – Mega Database Update - Byung Nam  
Stat Working Group – who to lead project TBD

**10. GCIG Studies/Updates/Issues**

No new updates

11. **AOB** – none raised.

12. **Meeting adjourned.**

Respectfully submitted,

Bette Stonebraker