



Harmonization Report

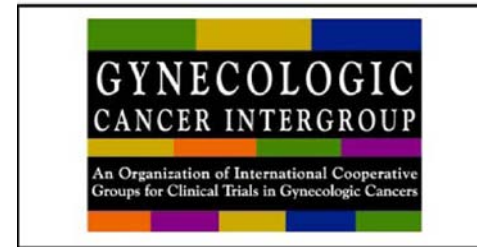
General Assembly 29 May 2015

Chicago

Harmonization: Operations group

- Ongoing business
 - Group Specific Appendix
 - Intergroup Agreement
 - Lead group matrix activity
 - Insurance/indemnity
 - Group contacts and summaries
 - Guidebook
 - Mentoring
 - Essential documents

WELCOME PACKAGE



A) Group Membership package

- 1.1. Information about GCI Membership – [Criteria to join to GCI](#).
- 1.2. GCI Governance Document and Statutes - [How is organized GCI and its members](#).
- 1.3. GCI Membership Committee Policy Document – [How the application will be evaluated](#).
- 1.4. GCI Membership Application form

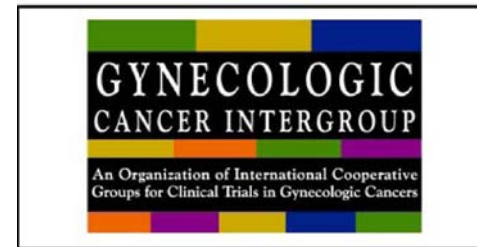
B) New member package

2. Harmonisation Guidebook. [What is GCI, Practical issues, SAE, Insurance, IDMC, DM, others](#).
3. GCI Harmonization Working Group, Group Contacts & Summaries: [How are Groups organized](#)
4. GCI Group Participation Summary: [What are groups doing within GCI](#).

Relevant information available in GCI website:

5. GCI meetings. Last meeting presentations. [Provide information of what GCI has done recently](#)
6. Principles of independence
7. Roster. [Identify contact data for each group](#).
8. Clinical Trials and Contacts. [To know what clinical trials are ongoing](#).
9. Groups web links. [Provide groups information \(including activities outside GCI\)](#).
10. Events. [Provide information of what is coming](#).

WELCOME PACKAGE



C) Collaborative Group Package:

1. Intergroup Agreement Template (Company Intellectual Property Acknowledgement and GCIIG/ Roles and Responsibilities). [Agreement for intergroup collaboration \(general frame\)](#).
2. Group Specific Appendix, GSA Guidelines. [Special agreements for project specific issues and the instructions for using it.](#)

D) Leading Group Package:

1. Data Monitoring Committees for GCIIG Trials. [Monitoring Board, mandatory for GCIIG Phase III trials.](#)
2. Checklist for Tissue Banking Consent Form. [Prevent essential information missing CF.](#)
3. Essential Documents Check-list. [Minimal requirements for CA approvals per Group.](#)

E) Educational Package and Tools:

1. CTCAE Submission Package
 - 1.1 CTCAE v4.0 Public Draft
 - 1.2. General Grades Guidelines
 - 1.3. Review Comments Template
2. CCRN Overview for Harmonization - June 2012
3. Neurotoxicity Binder

STATUS	TRIAL NAME	ACRIN	AGO	AGO-AUST	ANZGOG	COGI	DGOG	EORTC	GEICO	GICOM	GINECO	GOG	GOTIC	ICORG	JGOG	KGOG	MaNGO	MITO	MRC/NCR I (UK)	NCIC-CTG	NO
Follow up	AGO-OVAR OP.3 (LION)		Lead	Collab												Collab	Collab	Collab			
?	ALIENOR		Collab								Lead										
Recruiting	OUTBACK				Lead							Collab									
Follow up	AURELIA		Collab				Collab		Collab		Lead				Pend			Collab			
Closed	CALYPSO		Collab	Collab	Collab			Collab			Lead						Collab	Collab			Collab
Closed	CHORUS																			Lead	
Recruiting	DESKTOP III		Lead	Collab					Collab		Collab					Collab	Collab	Collab			
Recruiting	EORTC 55994		Collab					Lead													
Closed	EORTC55041			Collab	Collab			Lead			Collab						Collab		Collab		
?	EWOC		Collab								Lead										
Recruiting	GOG213											Lead									
Closed	GOG233/ACRIN 6671	Lead										Lead			Collab	Collab					
Follow up	GOG240								Collab			Lead					Collab				Collab
Follow up	GOG252											Lead									
Recruiting	GOG262											Lead									
Recruiting	GOG263/KGOG-0801											Lead				Collab					
Follow up	ICON6				Collab				Collab											Lead	Collab
Closed	ICON7		Collab		Collab				Collab		Collab									Lead	Collab
Recruiting	ICON8				Pend					Collab				Collab		Collab				Lead	
Recruiting	INTERLACE									Collab	Collab										
Recruiting	IPoc														Lead	Collab					
Recruiting	JGOG3017										Collab				Lead			Collab			
Recruiting	KGOG 2015															Lead					
Recruiting	mEOC						Collab					Collab					Collab	Collab	Lead		
Follow up	MITO CERV 2																		Lead		
Closed	MITO12																Collab	Lead			
Follow up	MITO7										Collab						Collab	Lead			
Recruiting	MITO8		Collab														Collab	Lead			
Recruiting	SHAPE																				Lead
Recruiting	NCIC CTG OV.21								Collab											Collab	Lead
In set up	NICCC							Pend			Pend										
Recruiting	OVAR 2.21		Lead	Pend	Pend						Pend										
Follow up	OVAR12		Lead	Collab			Collab		Collab		Collab						Collab	Collab			
Follow up	OVAR16		Lead	Collab	Collab				Collab		Collab			Collab	Collab	Collab	Collab	Collab			
Recruiting	PARAGON				Lead																
Recruiting	PORTEC3				Collab		Lead										Collab		Collab	Collab	
Recruiting	RTOG-0724											Collab									
Closed	SCOTROC4				Collab																
Recruiting	SYMPTOM BENEFIT		Collab		Lead	Collab					Collab		Collab	Collab	Collab			Collab	Collab		
Recruiting	TACO									Collab						Lead					

Harmonization: Operations group

- Liasons and Visitors
 - ENGOT report – Gabriele Elser
 - BIG - Sabine Cocheran
 - Lung Integroup – Paul Mitchell
- New business
 - Budgeting trials
 - Managing communciation during a trial

Harmonization: Operations and Statisticians

- New business
 - Risk-based monitoring - Bénédicte Votan
 - Clinical Trial design with biomarkers- Byung Ho Nam
- Ongoing
 - Publication joint manuscript
 - Megadatabase
 - Quality Assurance

Harmonization: Operations and Statisticians

- Liason reports
 - Translational Research
 - Materials transfer agreement
 - Materials transfers services agreement
 - Symptom benefit
 - Endometrial study
- Incoming Chair – Bette Stonebraker
Co-chair - Bénédicte Votan

See you in Tokyo!