WELCOME PACKAGE
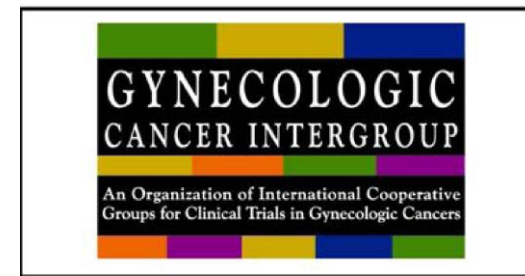
A) Group Membership package

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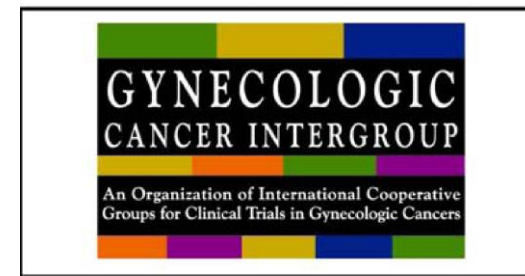1.4. GCIG Membership Application form

B) New member package
2. Harmonization Guidebook. What is GCIG, Practical issues, SAE, Insurance, IDMC, DM, others.
3. GCIG Harmonization Working Group, Group Contacts & Summaries: How are Groups organized
4. GCIG Group Participation Summary: What are groups doing within GCIG.

Relevant information available in GCIG website:
5. GCIG meetings. Last meeting presentations. Provide information of what GCIG 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 GCIG).
10. Events. Provide information of what is coming.

WELCOME PACKAGE

C) Collaborative Group Package:

1. Intergroup Agreement Template (Company Intellectual Property Acknowledgement and GCIG/ 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 GCIG Trials. Monitoring Board, mandatory for GCIG 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