GYNECOLOGIC CANCER INTERGROUP

An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

CURRENT STATUS

Harmonisation Information available at GCIG website:

Harmonisation Guidebook. What is GCIG, Practical issues, SAE, Insurance, IDMC, DM, others.
Appendix 1: Intergroup Agreement Template (Company Intellectual Property Acknowledgement and GCIG/ Roles and Responsibilities). Agreement for intergroup collaboration (general frame).
Appendix 2 : Data Monitoring Committees for GCIG Trials. Monitoring Board, mandatory for GCIG Phase III trials.
Appendix 3: Checklist for Tissue Banking Consent Form. Prevent essential information missing CF.
Appendix 4: Essential Documents Check-list. Minimal requirements for CA approvals per Group.
Harmonization Working Group, Group Contacts & Summaries. How are Groups organized.
Group Participation Summary. What are groups doing within GCIG.
Group Specific Appendix, GSA Guidelines. Special agreements for project specific issues.
Summary of EDC and archiving by GCIG Groups. EDC and archiving electronic data capability.

Other Information available at GCIG website:

Principles of independence.
Membership policy.
Governance and statutes. GCIG publication statement
GCIG meetings. Last meeting presentations. Provide information of what GCIG has done recently
Roster. Identify contact data for each group
Clinical Trials and Contacts
Groups web links. Provide groups information (including activities outside GCIG)
Events. Provide information of what is coming

Background

- GCIG wants to be assured of quality in trials it endorses
- GCIG member groups have agreed to comply with GCP and to document centers' trial staff are GCP trained /compliant
- *Groups Contacts and Summaries* describe procedures /processes for monitoring and auditing within each group

Logistics/resources

- Each trial site should be audited once every 3 years by a participating trial group, preferably within the same region, for adherence to GCP.
  - 1000 + sites ?
  - 3-5 days/audit
  - Resourcing

- Each participating trial group should be externally audited once every three years to ensure adherence to GCP.
  - 23 groups @ 3-5 days/audit
  - Resources
  - Auditing body

- Each trial site should be monitored at least once during the conduct of each GCIG trial according to agreed SOPs, measures to correct major deficiencies advised and remonitoring to take place within one year.
  - 100s of sites
  - Minimum 3 days/monitoring (including prep, visit, followup)

Current status

- Sponsor has overall responsibility for trial conduct including quality assurance (lead group or delegate)
- ICH E 6 , Section 5
- Trial based QA plans evaluated on level of risk
- Increased intensity for any safety, conduct, quality issues during trial conduct

Supporting documentation/guidance

- *Intergroup agreement*
  - Declaration of GCP adherence
  - Roles and responsibilities
  - Protocol and appendices

- *Group specific appendix*
  - Monitoring and auditing
  - Safety
  - Pharmacovigilance

- *IDMC charter*

Educational support

- *GCP training module*
  - AGO model
- *Mentoring plan*
  - New GCIG groups
  - First-time lead groups
- Support for
  - Specific concerns
  - Research addressing quality issues