GYNECOLOGIC CANCER INTERGROUP

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

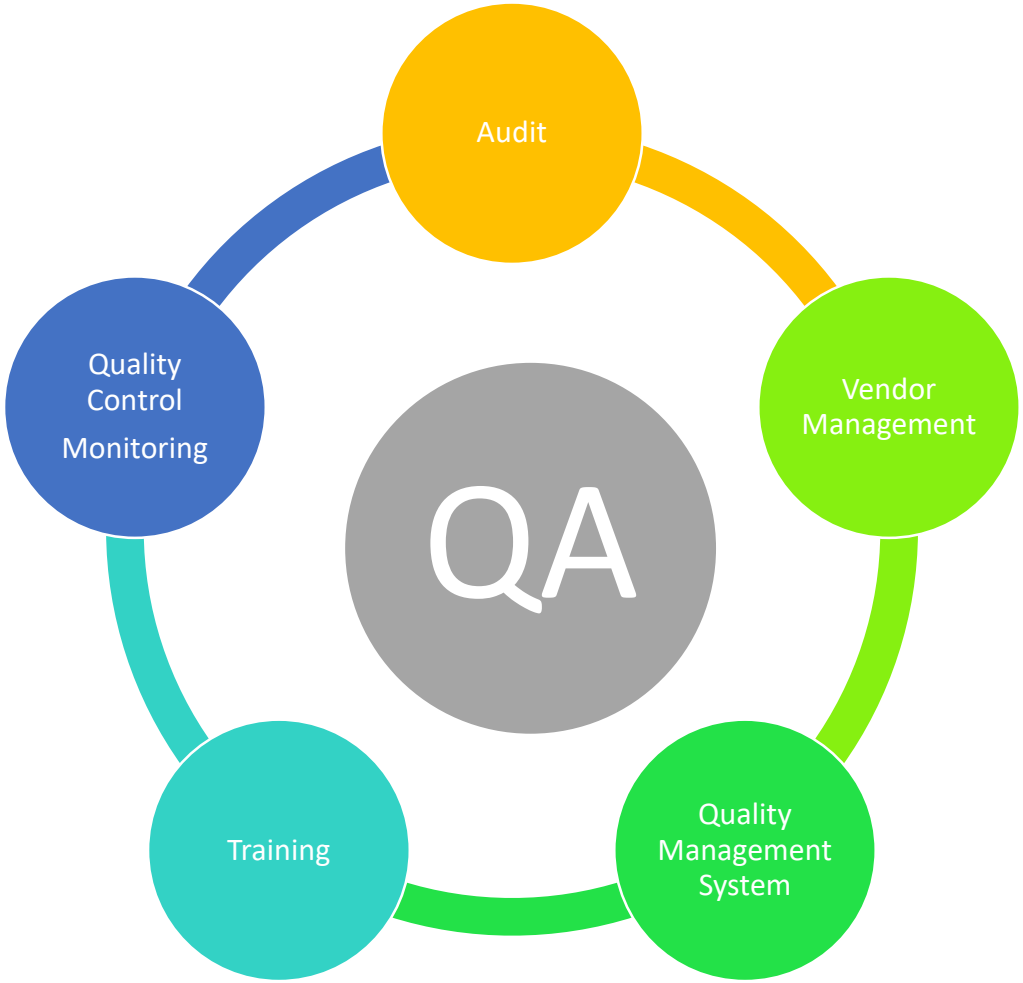
Gynecologic Cancer InterGroup FINAL

QUALITY ASSURANCE BRAINSTORMING and EDUCATION DAY

November 2, 2017, 8:00am – 3:00pm, Medical University of Vienna

Chair: Jane Bryce Co-Chairs: Alison Brand and Laura Farrelly

QA – Quality Assurance



OBJECTIVES OF DAY:

1. Consensus on minimum evidence of GCP compliance
   - Vendor Assessment – “Participating Group”, “Laboratories”, “Generic”
   - Site qualification by group

2. Standards for Centralized Monitoring

3. Strategies for overcoming persistent regulatory obstacles in GCIG trials

1. Consensus on minimum evidence of GCP compliance

- Requirement for vendor assessment . Tool in development by QA/Harm group. Final draft end 2017
- Other tools will be linked to this document (Intergroup agreement with Roles and Responsibilities, , Site qualification, Site selection)
- Consideration of vendor audit tool

2. Standards for Centralized Monitoring

- Central monitoring should be RISK-BASED
- Get sites on board by explaining benefits (should be less work, not more)
- Minimise expense (eg use eCRF as basis for monitoring)
- Both vendor assessments and site assessments should be part of a risk based strategy
- Measure data collected against identified risks of the study (statistical assessment)
- Quantify risk– high/medium/low
- Define and specify minimum standards (varies with different trials)

2. Standards for Centralized Monitoring: Minimum monitoring plan

Patient and trial safety

DATA CHECKS

• Eligibility and stratification factors	every patient (100%)
• Endpoints	every patient (100%)
• Intervention as per protocol	every patient (100%)
• Safety / toxicity (AE and SAE, type/grade)	depends on the trial (risk assessment determines %)

STATISTICAL

• Define areas of statistical monitoring for trials	per trial

Regulatory aspects

• GCP compliance, regulatory documents	annually or at start and midway

3a. Regulatory:

Insurance:

- **Request a level of cover (or respect of local legislation) plus additional cover with limitation of liability by contract; (**unlimited liability of some jurisdictions is a potential no go)

Sponsorship

- Co-sponsorship can be considered
- Agreement is the solution (you need to make sure though that the other Party is able to abide by the contract

3a. Regulatory:

Tissue samples

- Legal issues are complex , Issues take too much time to resolve; solutions are expensive
- Problems of transferring samples from some regions or even from one site to another in the same country; regional/national hub may be a solution; upfront contract seems to help; IP to be shared

Other issues

- Language/translation difficulties, length of PIS. Would consumer input help?