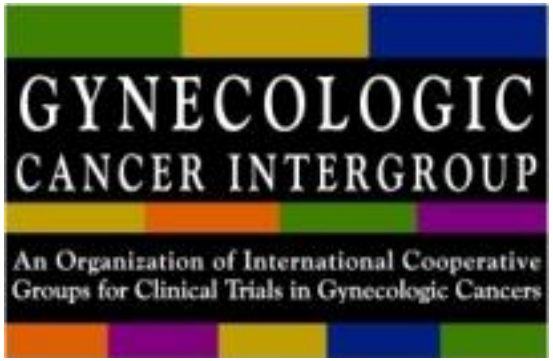

Quality Assurance Working Group

General Assembly 3 June 2016

Chicago

Quality Assurance working group:

- Thanks to Quality steering group for work from Strategic Planning 2015
  - Marth, Hardy, O'Donnel, Pignata, Stonebraker, Bryce
- Exec Committee established QA WG, and requested that all member groups name 1 representative to the WG
- Initial meeting 2 June 2016
  - Badging a GCIG trial
  - GCP addendum
  - Creation of a monitoring / auditing / network / panel
  - QA educational proposal for 2017 autumn meeting

Badging a GCIG trial
according to current GCIG documents…

- can be proposed by one or several groups
- **trial has peer review (independent ? TSC)**
- can be funded by industry but not conducted by industry
- 2 or more GCIG groups collaborate.
- Non GCIG groups may participate, but not be lead group
- **single protocol**
- **single set of CRFs**
- **data collected in lead group data center**
- **data analyzed by lead group Data Monitoring Committee**
- **data shared with collaborating groups**
- not conducted by industry
- Independent reporting of trial results (independent from industry , even if funder)
- Trial Steering Committee can name Lead group in cases where more than 1 groups proposes
- **conducted in GCP**
- Lead group and participating groups sign "Intergroup agreement“
- **Lead group responsibile for QA plan for trial**

GCP addendum

- Proposed in 2015, open comment period closed, release final version release expected by end of 2016
- Selected topics:
  - Investigator responsibilities
    - Responsible for oversight of staff and site, with verification of qualification and procedures to ensure data integrity/human subject protection
  - Sponsor responsibilities
    - Risk based total quality managment (design, conduct, recording, evaluation, reporting and archiving of clinical trials)
    - Oversight of electronic systems (certification), CROs, and follow-up for non-compliance

Monitoring / auditing Network / Panel

- Discussion of possibility to create a GCIG network of experts in compliance issues
- Some aims:
  - Establish uniformity in monitoring for specific trials
  - Resources with expertise for regional issues (language, regulatory issues, etc)
  - Possible use for auditing / education for groups to assess QA processes

Proposal: QA education fall meeting

- ICH-GCP
- Insurance / indemnity
- Nat'l regulatory authorities
- Ethics
- Pharmacovigilence/safety
- Principles of independence
- Badging
- Agreements
- Site credentialing
- Industry
- RDC systems certification
- DMC
- Pathology spec and reviews
- Radiation therapy
- Surgery
- Monitoring
- Auditing
- Group assessments/audits
- Monitoring network
- Intellectual property-pubs
- Other…