GCIG Quality Assurance Working Group
27 Oct 2016

Agenda:

- GCP addendum
- GCIG minimum standards of quality
- ANZGOG experience

ICH E6 addendum

- 26 items of change -> all in the addendum
- Core document not open to revision
- Expected to be final end of this year (NOV)

Summary of changes

- Investigator oversight of their site
- Source documents
  - ALCOA - Attributable Legible, Contemporaneous, Original and Accurate
  - ALCOA**C** - + Complete
- Recording of location of documents by sites
- **Sponsor oversight of vendors**
- **Quality management – risk based**
- **Risk based monitoring**
- Serious breaches to the protocol or GCP
- TMF may contain more that ICH E6 s 8
- Monitoring plan and monitoring report
- Electronic systems and data handling

Discussion and action plan - 1

- Vendor assessment
  - Who are vendors ? partner groups, CROs, laboratories, etc
- To what extent do you evaluate vendor – group?
  - Is self-report and group provision of documents (SOPs) or list of documents or critical processes ?
  - Is peer review or audit or certification required?

- **ACTION: Propose minimum standards for vendor assessment**
  - Basic vendor assessment tool, with specific modules related to services (GICOM, SGCTG)
  - Partner group assessment tool (PMHC, MITO)

Discussion and action plan -2

- Suggested minimal QA standards for GCIG groups?
  - Evidence of GCP compliance
  - CVs, training, audits, inspections..?
  - Collection of Groups SOPs for monitoring and auditing

- **ACTION:** Focused groups survey within 2016 regarding practices and acceptable minimal (documentable) standards for evidence of GCP (MITO, ANZGOG)

- **ACTION:** Propose minimum standards for:
  - Centralized monitoring (AGOG, NCRI, GOG)
  - Initial site assessement and approval (one-time done by groups for their sites, not trial specific (COGI, NSGO)