GYNECOLOGIC CANCER INTERGROUP (GCIG)
QUALITY ASSURANCE WORKING GROUP

THURSDAY, OCTOBER 27, 2016, 4:30PM – 5:30PM
AUGUSTA II ROOM, DoubleTree Fontana Hotel, Lisbon
Chair: J. Bryce Co-Chair: A. Brand

Meeting minutes

Attendance: Jane Bryce MITO (JB), Alison Brand ANZGOG (AB), Anastassia Negrouk EORTC (AN), Laura Farrelly NCRI (LF), Adriana Chavez GICOM (AC), Chantelle Blattler PMHC (CB) , Benedicte Votan GINECO, Nelleke Ottevange EORTC (NO), Rund Bekkens, Chyong-Huey Lai AGOG (CL), Lan-Yang Yang AGOG (LY), Pei-Jen Chang COGI (PC), Teri Longacre COGI , Eva Roennegart NSGO (ER), Eve Peeraer BGOG, Maren Keller NOGGO, Regina Berger AGO-Au
Regrets: Andrea Hiltz CCTG (AH), Bom Choi KGOG (BC)

Topics

1. **GCIG Trial badging**
   Prior to meeting via email discussions with Executive, It was decided that badging was not within the QA group remit.

2. **GCP addendum update**
   AN gave a presentation about the upcoming release of the ICH GCP addendum (ICH E6 (R2) step 2b. The addendum will be adopted late 2016 / early 2017.
   2 areas of focus for QA groups are:
   a. Sponsor oversight of vendors: Vendor assessment is part of the expected oversight. – this could include not only CROs, laboratories but also partner groups (i.e. collaborating GCIG groups).

   ACTION 1: Working group to propose minimum standards for vendor assessment. First draft to circulate by end of Dec 2016
   - Basic vendor assessment related to services (AC, KC)
   - Partner group (collaborative group) assessment tool (CB, JB)

   b. Risk-based quality management, including risk-based monitoring. This topic has been discussed at previous QA meeting, and Harm/Ops meetings.

   ACTION 2: Working group to propose minimum standards for centralized monitoring based on risk assessment of trials. (LF, CL/LY, BS, NO). First draft to circulate by 15 Jan 2016.

3. **Suggested minimum QA standards for GCIG**
   Suggested were; evidence of GCP compliance (through CVs, GCP certification, audits, inspections). Many differences in groups came forth in discussion and in Auditing and monitoring summaries extraction of Group summaries document of Harmonization Committee.
   AB presented ANZGOG recent experience of an ANZGOG QA workshop and the development of risk-based monitoring minimum criteria, as well as initial assessment of an ANZGOG site.

   ACTION 3: Focused groups survey regarding practices and acceptable minimal documentable standards for evidence of GCP (JB, AB, LF) Survey to be distributed within December 2016.

   ACTION 4: Propose minimum standards for initial site assessment and approval (one time done by groups for sites, not trial specific (PC, ER, AH , BC) First draft by 15 Jan 2017.