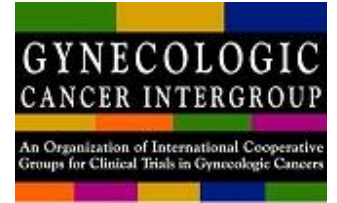


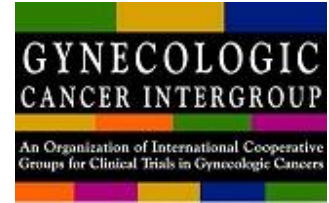
Harmonization Ops And Ops/Stats Committee Meetings

May 30-31, 2018

**Bette Stonebraker, chair
Benedicte Votan, co-chair**

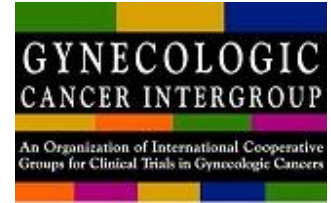


GCIG Strategic Planning Harmonization Ops Committee



- Previous Projects Completed and Posted to Website
- Concentration on Educational Sessions:
 - Dr. David Millan presented Pathology Manual on behalf of the ISGyP and the importance of accurate diagnoses prior to patient entry onto study, especially in rare tumor or specific subtyping
 - Regina Berger (AGO Au) presented the new EU Data Protection Plan and its global implications
 - Dr. Mansoor Mirza presented the UMBRELLA trial, clarifying numerous procedural and logistical questions from Committee members
 - Yusuke Kajimoto (GOTIC) presented us with an introduction to Financial Toxicity to be further addressed in future meetings

Harmonization Ops & Ops/Stats Committee Meetings



- Discussion regarding Committee Goals for Strategic Planning Meeting
- Incorporate QA Working Group back into Harmonization
 - Refine Vendor Assessment tool
 - Continue to expand Risk-based Monitoring documents as appropriate
 - Harmonize with CCRN regarding Regulatory Issues
 - Explore new areas such as Group Audits, Group Evaluation documentation
- Discussion to work with Stats and Meta Analysis WG to create a survey to identify common data elements