GCIG Harmonization Group Meeting Minutes 3 June 2010 Chicago

Present: tbc

1. **Welcome and Introduction:**
2. **Approval of minutes:**
3. **Minuter:** Bette Stonebreaker
4. **Group contacts & Summaries:**
5. **Next meeting:** to be held in Prague, Czech Republic, Oct 21-22, 2011.
6. **Operations/Data management issues:**

- CDEs --- Brian Campbell from EMMES/NCI US joined us by teleconference and gave an update on CDEs. All non-US GCIG groups intend to attempt to continue to include as many CDE variables as possible in future data collection for the studies they lead (to facilitate meta-analyses) BUT many continued to **not agree** to use the CDE-specific questions (terminology) as the meanings are not always the same to foreign tongues. Brian remains available for consultation.
- CTCAEv4 --- Brian Campbell also updated us on CTCAEv4 and answered questions. Again, most groups agreed to continue to utilize CTCAEv4.
- The Committee is collecting Group Specific Appendix templates from all groups (who have such) and the plan is to develop a generic template for guidance (especially for those groups new to this game).
- Informed Consent -- signature pages --- the majority of the other groups use a PIS (Patient Information Sheet) combined with a one page Consent Form (which identifies the version of the PIS). So, they already either collect or audit only their one-pager.
- Signatures on CRFs --- the majority of the other groups continue to require Investigator signature on each CRF. The complication of EDC/RDC is under consideration/discussion.
- E.U. Pharmacovigilence/Eudravigilance --- the majority of the experienced European groups stated that one of (however many) "participating" European groups will do the Eudravigilance for all of them per non-EU-led intergroup study (to be decided amongst themselves). They said that only immediate individual reporting of EU patients' SAEs is required; annual report from the lead group on world wide study-specific SAEs would be forwarded to Eudravigilance by the EU group taking that role. In fact, other non-EU groups were emphatic that they would not take on that national regulatory responsibility for EU participating groups. [eg: upcoming GOG study being joined by ANZGOG, NSGO, EORTC and MITO --- EORTC will do eudravig. for themselves and NSGO and MITO.] Part of confusion is the word "sponser"; in NAmerica this is "submitter/holder of IND/CTA" ; in Europe it is also (primarily) "funder". Thus, in Industry-run (vs academic) studies where Pharma is both types of "sponser", then Pharma does all the national regulatory responsibilities for all participating countries, including SAE reporting (to Eudravig. & Health Canada & CTEP & so on).
  Shoe on other foot --- EU groups do not want to take on that national regulatory responsibility for overseas participating groups (eg: Australia or USA or Canada) if EU group is lead.

7. **Meeting adjourned.**