ADDENDUM TO GCIG HARMONIZATION WORKING GROUP MINUTES OF MAY 12/05

7. Intergroup Agreement

- **Discussion:**
  - This document is made to be a template; it is flexible in as much as it may need to be.
  - The use of wording such as 'Sponsor' and 'Legal Representative' are to be used for all entities and countries.
  - A definition of who the entities are should be referred to in the protocol (eg: CALYPSO protocol).
  - A new section referring only to pharmacovigilance reporting should be created. A working group is to be formed to review the exact wording and different processes of reporting throughout the groups.
  - It was suggested that a separate section for insurance and indemnity be created also. Some were in favor of this, others not
  - Information regarding the formation of a Trial Steering Committee and Data Management Committee is valid, but for large trials this may be more or less realistic. Groups will assess on a per needed basis if either one of those committees needs to be formed for their trials. It is noted that neither one of those committees are mandatory, but can be helpful.
  - Comments were made on the definition of each committee: the **Trial Steering Committee** provides oversight of the study, and receives any recommendations made by the IDSM; the **Trial Management Committee** makes decisions about the study and relays this information back to the Sponsor.
  - These committees should have as their goals: review of topics such as the database, intellectual property and translational data.
  - All groups are in agreement to use this Intergroup Agreement (minus EORTC and GEICO, not present at this meeting) as a contract template.
- **Resolution**
  - The only sections that need modifications are those on database, intellectual property, inventions, and insurance. A separate appendix will be created for pharmacovigilance reporting and instructions. (Action: Swart)
  - A document entitled Roles & Responsibilities will also be used in the future and appended to the Intergroup Agreement for better understanding of responsibilities of all in the conduct of the study.
- **Other Points**
  - As it has proven generally better to have only one master protocol managed and updated by the "Sponsor", a sample of a complete informed consent document should always be included in the protocol's appendices, and then modified per each country's specific needs. It is recommended that an appendix be attached which can include local procedures as well as the local Informed consent, without changing the master protocol.