GCIG Harmonization Group Meeting Minutes 10 October 2009 Belgrade

Present:		Absent:
AGO OVAR	G Elser (GE), A. Reuß	
AGO Austria	B Kunz	
ANZGOG	J Martyn (JM)	V.Gebski
DGOG	E Witteveen	
EORTC	---------	D.Lacombe, B.Penninckx
GEICO	F Nepote	
GINECO	N LeFur, B Votan	
GOG	Stonebraker (BS), M Brady	
JGOG	E Aotani	
MaNGO	R Fossati	
MITO	J Bryce (JB)	
MRC	L Farrelly (LF), W Qian	
NCI US	----------	
NCIC CTG	M Bacon (MB), D.Tu	
NSGO	G Andersen (GA)	
RTOG	A Jhingran (AJ)	K.Winter
SGCTG	J Paul (JP),, K.Carty (KC)	
SWOG		G.Anderson
Website/Emmes	M Schoenfeldt (MS)	
Tahio Pharmaceuticals	K. Morinaga	

1. **Welcome and Introduction:** GE welcomed all to the meeting and called meeting to order.
2. **Approval of minutes:** from meeting 28 May 2009 Orlando were approved (JB and JM)
3. **Minuter:** JB (MITO) offered to write the minutes of the current meeting
4. **Group contacts & Summaries:** DGOG is now active in the GCIG and in Harmonization Working Group
5. **Translational Research:** During meeting JM solicited from members comments on many national regulatory issues related to release of biological specimens for translational research including:
    a. JGOG does not permit any cross border movement of specimens
    b. Spain, Italy and Netherlands require Ethics Committee approval and detailed informed and privacy consents for specimens
    c. France requires formal submission to Competent Authority in a process that takes several months

    JM will follow up with survey of group

6. **Updates from last meeting:**
    a. BV led discussion about Declaration of Helsinki issue of informing participating patients of trial results. In general, group noted that although trials may be registered in an international trial registry (ie ClinicalTrials.gov) where results are also posted, it is not clear that patients refer to the site after enrolled in a trial. Further an English language website may not be a suitable place for patients to seek information about results of the study in which they have participated. General agreement that large intergroup trials

could have an lead group PI letter generated to each group, that could then be adapted to patients of participating countries and Ethics Committees as per group standard. The following procedures are currently used:

i. **NCIC,AGO, JGOG** report that results are disseminated to individual Investigators who then discuss with patients. JGOG requires that Investigators document this discussion.
ii. **UK** any discussion with patients is done after publication of study results, the Sponsor provides a written letter that can be given to patients
iii. **GOG** posts trial results and may provide letter of information
iv. **MITO** results must be sent to EC, practice varies

BS will circulate a GOG template for discussion

b. BS led discussion of Implementation of CTCAE 4.0, which most groups are integrating with new protocols. BS referred that NCI plans yearly updating of CTCAE version, with implication that changes can occur during trial (no longer a static version), and will ask for a representative of NCI CTCAE group to speak at next Harmonization meeting.

7. **Quality of Life instruments**: discussion of most common instruments being used to assess patient reported outcomes (PROs) are EORTC QLQ 30 and OV-28, FACT-G, ovary and cervix and neuro GOG subscales, and supplemental diary cards. AJ will ask Kathlyn Winter to collect for next meeting.

8. **Successor HG Working Group:** GE is resigning as Chair of study group and representative to GCIG. All applauded her noteworthy contributions and leadership to the Harmonization Working Group. Pending Executive Committee approval, JM (ANZGOG) has offered to Chair the group, and JB (MITO) offered to coChair. Group members in attendance unanimously favored the selections. GCIG has committed to providing travel funds to guarantee presence of group Chair or Cochair for attendance at meetings

9. **Future directions:** JB reviewed ongoing status of MITO nursing study, and MB discussed the nursing study of OV-21. Interested participants should contact JB or MB or respective websites.

10. **GCIG study issues** all representatives provided updates on active GCIG trials

11. **Group identified issues:**
    a. Remote data capturing (RDC) archiving needs to be followed up
    b. CDE's revisions and comments sent by MB to Executive Committee
    c. Ongoing trial updates should be sent to MS for the website

12. **Next meeting:** to be held in Chicago, USA June 3, 4 2010.

Operations/Data management issues:

a. **Survey of monitoring/queries/deficiencies (MB)**
b. **Protocol deviation / violations (JB)**

The surveys regarding these issues were not able to be completed by all groups. A lengthy discussion was held about the various issues of how deficiencies, deviations and violations are handled and potential impact on study outcome data, also demonstrating the need to carefully plan a questionnaire that permits better evaluation of group practices. Also agreed, it is important to include statisticians in both survey development and individual group responses. JB and MB will work on more comprehensive survey to be presented subsequently. Suggestions, SOPs or policies from any groups are welcome and should be sent to JB or MB.

Template group specific appendix: minimum requirements for a group specific appendix should be sent to LF.

Secure emails GA suggested agenda item next meeting for discussion of issues related to secure emails and protection of sensitive data sent digitally.
Meeting adjourned.

Respectfully submitted,

Jane Bryce
Gabriele Elser