GLOBAL HARMONISATION TASK FORCE

STUDY GROUP 5 – CLINICAL EVIDENCE

Minutes of Meeting Monday 19 May to Wednesday 21 May 2008

JFMDA Offices
8th Floor, Iidabashi Square Bldg.
3-2, Shimomiyabicho, Shinjuku-ku
Tokyo 162-0822, JAPAN

A meeting of the Global Harmonisation Task Force (GHTF) Study Group 5 was held at the offices of the JFMDA, Tokyo, Japan on 19-21 May 2008.

Attendees at the meeting were:

Susanne Ludgate, MHRA, UK
Greg LeBlanc, MEDEC, CANADA
Atsushi Tamura, PMDA, JAPAN
Christophe Bailleul, Eucomed, BELGIUM
Richard Pembrey, TGA, Australia
Kazuhiro Sase, Juntendo University Medical School, JAPAN
Herbert Lerner, FDA, USA
Yoshihiro Noda, JFMDA, Japan
Benny Ons, EDMA, Belgium
Peter Rattke, COCIR, Austria
Mitchell Krucoff, Duke University Medical Centre, USA
Mark Gordon, AdvaMed, USA

Item 1 Welcome and Introductions

The meeting was convened by the Chair, Dr. Susanne Ludgate. All members were thanked for their attendance, and introductions were made.

Item 2 Adoption of Agenda

The draft agenda circulated in advance of the meeting was deemed suitable. It was agreed to include a brief discussion of the concept of "maintenance mode" for the group under "Other Business". Thus, the following agenda was adopted:

1. Welcome, introductions and housekeeping information
2. Adoption of agenda
3. Discussion of Minutes from previous meeting and matters arising

4. Discussion of Post-Market Clinical Follow-Up Document
5. Discussion of Adverse Event Reporting Within Clinical Investigations and SG2 N54 Document
6. Other business
7. Next meetings

Item 3 Discussion of Minutes from Previous Meeting and Matters Arising

The minutes from the last meeting had been previously circulated and accepted via e-mail. A brief review of the minutes was conducted and the following updates were provided:

Item #6 – re: STED and Clinical Evaluation (N2) Document Interface – The Steering Committee review of the STED is continuing. The SG5 suggestions discussed at the last meeting were accepted by SG1.

Item #7 – re: Glossary document – discussions around the "conflicting" terms have been held but no further update at this time.

Item 4 Discussion of Post-Market Clinical Follow-Up Document

The group discussed the comments that had been provided as a result of the circulation of the documents within the various member jurisdictions. These comments were incorporated into the document as was felt suitable. Following this process, the group concluded that the document was ready to be put forward to the Steering Committee for advancement as a Proposed Document for public comment, and that this should be done in time for the Steering Committee's next meeting.

There was concern expressed over the lack of a harmonized definition of "Post-Market Surveillance", with some members expressing the view that this may hamper our document. It was felt that this was a term that should be defined most appropriately by SG2, and that feedback in this regard would be provided to the Steering Committee and SG2.

Item 5 Discussion of Adverse Event Reporting Within Clinical Investigations and SG2 N54 Document

The group was updated regarding feedback from the Steering Committee that the issue of Adverse Event Reporting within Clinical Investigations was best pursued within SG2, and subsequent discussions between the Chairs of the two groups. It had been determined that the first step in tackling the issue would be for SG5 to conduct a review of the existing SG2 N54 document, and provide feedback on how it might be adapted or used as a starting point for work on the issue.

The members of SG5 agreed that the major points needing to be addressed were a common set of definitions around what is reportable, the timing of reports, and to whom AE's should be reported.

A review of the SG2 N54 document was conducted, and some observations discussed. It was agreed that the definition of what is reportable as outlined was probably sufficient, however, the general consensus was that there are some significant gaps that would need to be addressed regarding the situation within the context of a Clinical Investigation. It was felt that the next step might be for a small group of two or three individuals from SG5 to attend the next meeting of SG2 in order to discuss the issues further. It was also suggested that perhaps the formation of a small *ad hoc* working group with members of SG2 and SG5 to tackle substantive work on the issue might be appropriate. It was agreed that these thoughts would be shared with SG2 and the Steering Committee.

Item 6 Other Business

Privacy Issues in the collection of Post-Market Clinical Follow-Up Data

There was a discussion of an issue that was brought to the attention of the Group involving the potential for conflict between jurisdictional privacy legislation and regulatory requirements for post-market clinical follow-up data collection. The consensus of the group was that this issue was likely too country-by-country specific for SG5 to address on its own. It was felt that this was beyond the scope of just SG5, but that it was an important issue that would be brought to the attention of the Steering Committee with encouragement that it be addressed in one form or another.

Maintenance Mode

A discussion was held over the fact that the active work of SG5 was winding down, and that it would soon be appropriate for the group to go into "maintenance mode". Some ideas were discussed on how we felt this would best be managed. Consensus was reached that twice-a-year teleconferences/web conferences would be appropriate, with face-to-face meetings being held only when necessary, aiming to coincide with other pre-established GHTF activities (e.g. conferences). This type of meeting cycle would allow us to continue to inform the broader GHTF stakeholders of our activities, and maintain group cohesion (which the group wanted to emphasize is an important part of the successful dynamic of our group). It was also agreed that it is important that the group continue to be representative and collaborative, and that undue emphasis should not be placed on any subgroup of representatives going forward.

Vice-Chair Term Expiration

It was discussed at the meeting that Greg LeBlanc's 3-year term as Vice-Chair of the group would be expiring shortly. In view of this, the group unanimously stated their preference that he continue in this capacity and that a consensus nomination to this effect should be presented to the Steering Committee.

ISO 14155 Latest Revisions

A brief discussion of the latest revisions to ISO 14155 was held. It was agreed that there do not seem to be many changes, but that there are a few additions. It seems to be moving more in the direction of a guidance document and is looking less like a standard. The group agreed that formal comment should be presented to the Working Group responsible of the standard.

Item 10 Next Meetings

The current schedule for upcoming meetings is as follows:

- London, UK, 3-4 November 2008
- Toronto, Canada, Spring 2009

The Chair and group expressed thanks to the Japanese delegation, especially Yoshihiro Noda, for the arrangements to host the meeting.

The meeting was then closed with thanks to all participants.