GHTF SG2- 40th Meeting
Location: GE Healthcare
Munzingerstrasse, 5 -79111 Freiburg
Date: September 14th -16th, 2010

Attendance:

Name	Organization	Email	14/09	15/09	16/09
Takehiko Arima (TA)	JFMDA	tarima@its.jnj.com	X	X	X
Philippe Auclair (PA)	EUCOMED	philippe.auclair@av.abbott.com	X	X	X
Mary Brady (MWB)	FDA	Mary.Brady@fda.hhs.gov	X	X	X
Pam Carter (PC)	TGA	Pamela.Carter@tga.gov.au	X	X	X
Isabelle Demade (ID)	EC	isabelle.demade@ec.europa.eu	X	X	X
Barbara Harrison (BH)	Health Canada	barbara_harrison@hc-sc.gc.ca	X	X	X
Bertram Koening (BK)	EUROM VI	bertram.koenig@bbraun.com	X	X	X
Yuta Maeda (YM)	MHLW	maeda-yuuta@mhlw.go.jp	X	X	X
Essam Mohandis (EM)	AHWP	EMMohandis@sfda.gov.sa	X	X	X
Barbara Mills (BM)	MITA	Barbara.Mills@ge.com	X	X	X
Carmen Ruiz Villar (CRV)	AEMPS Spain	cruizv@aemps.es	X	X	X
Michael Santalucia (MS)	AdvaMed	Michael.a.Santalucia@bausch.com	X	X	X
Klaus Stitz (KS)	MEDEC	kstitz@medec.org	X	X	X
Ekkehard Stösslein (ES)	BfArM	e.stoesslein@bfarm.de	X	X	X
Miang Tanakasemsub(MT)	AHWP	miang.tanakasemsub@zimmer.com	X	X	X
Hiroyuki Tanishiro (HT)	PMDA	tanishiro-hiroyuki@pmda.go.jp	X	X	X
Observers					
Bernard Carrichon	GE Healthcare		X	X	X
Joachim Huber	GE Healthcare		X	X	
Ms. Ayumi Kishi	PMDA	kishi-ayumi@pmda.go.jp	X	X	X
Eng. Dulce maria Martinez Pereira (DMMP)	CCEMM	dulce@cceem.sld.cu	X	X	X
Rainer Voelksen	GE Healthcare				X
Hideto Yokoi	MHLW	yokoi@med.kagawa-u.ac.jp	X	X	X
Expert invited by Chair :					
Ben Khosravi (BK), Advisor	St Jude Medical (SJM)	bkhosravi@sjm.com	X	X	X
Members-excused					
Tanaka Daisuke (TD)	MHLW	Tanaka-daisuketd@mhlw.go.jp			
Hiroshi Ishikawa (HI)	JFMDA	hiroshi4.ishikawa@toshiba.co.jp			

1. Welcome, Introductions, Announcements

Day 1 of the **40th meeting of GHTF Study Group 2** began at 11:00 AM on September 14th, 2010, with a greeting from the Chair, **Dr. Isabelle Demade**, (EU Commission) extending thanks to GE Health Care for hosting the meeting.
New members (or replacement attending this meeting) and observers introduced themselves and were welcomed by the group.

2. Review meeting agenda. Minutes from the previous SG2 meeting

The draft agenda was adopted

Minutes from the Valencia meeting were approved (document N122) with rewriting of the ICSR (or Individual Adverse Event report) section and a correction on typos.

Following the recent changes in membership, it was decided to update the membership list posted on the GHTF SG2 website

- Actions :
  - Final minutes Valencia N122. Distribute final version and ask posting on web site
  - List of Members. Circulate list for checking and require posting on web site

3. Review of the actions items from the last meeting

Action items from the previous SG2 meeting were reviewed. The Chair noted the excellent progress and placed emphasis on the two major work items:

- N111 (Definition and classification of Field Safety Corrective Actions -FSCA- , including recalls)
- Guidance on Adverse Event occurring during clinical investigation developed in common with SG5

4. Report on GHTF Steering Committee Activities.

I Demade reported on the latest SC teleconferences highlights:

- The steering committee expects the first part of N111 – definitions of FSCA, including recalls – to be available for a first review by the end of 2010
- The training document. N120 was circulated for information and should be finalized before the Sydney meeting of the steering committee (November 2010)

5. GHTF SC PD N1R6- Regulatory model- ID

Comments from the group were discussed. Suggestions were made for a modification of Figure 8. A revised Fig 8 was circulated and reviewed. Some changes requested .In parallel, a new wording of section 10.2 was agreed.

- Actions
  - Finalize Figure 8 changes and new wording of section 10.2
  - A subgroup to review the text of the whole document and provide their comments to the Chair
  - After review of the final comments, SG2 comments to be brought to the attention of the Ad Hoc Working Group in charge of the document

6. N111 - Definition and classification of Field Safety Corrective Actions (FSCAs), including recalls.

6.1 N111- Part 1 Definitions- PC and team

The group reviewed all comments received on the previous version. A new format has been agreed, and examples reviewed and modified.

- Actions :
  - N111 part 1- (now 111-R5. Sept 15, 2010), to be cleaned and re-circulate to the group

- Final comments to be gathered and the document to be sent to the steering committee

6.2 Status document of requirements in the GHTF Founding Members. (N119)
The document was prepared /reviewed by BH.

Action :
- Check format, re number (N119 R4) and circulate the document for approval as status document at the next meeting

6.3 N111_ Part 2 Classification- working document- PC and team
The sub group working on the document presented the various inputs and proposals. Classification is now in 3 categories based on risk of recurrence and severity of the AE. Examples have been reviewed and modified.

Actions :
- Revised document to be circulated
- Subgroup to prepare the final version for approval at the next meeting.
- Produce a flow process mapping classification examples and definitions

7. Standardization activities

7.1 Follow up on N87- e-reporting pilot developed by the EU
ES updated the group on the electronic format. The following European Member States have an agreement of principle to move toward acceptance (UK/IE/FR/Spain). The model is available for other geographies.
Convergence between N87 and HL7: the XML codes are not totally aligned with the HL7 codes. The latter is used by US FDA for its e-reporting project; it is not used in the Japanese reporting system.
AHWP is developing an e-form and is considering starting with a simplified form and later converging to a more complex and harmonized system.
The project to have a mapping of the N87 XML codes and the HL7 codes was undertaken on a voluntary basis by BfArM and FDA and is now on hold due to lack of resources.

It is also decided to include harmonization across geographies of e-reporting system in the internal document N73 (SG2 doc on Implementation of SG2 guidance). .

Actions :
- Circulate N73 with an additional row for harmonization with N87 for tracking e-reporting harmonization
- Provide a description of the compatibility issues between HL7 and N87
- Produce an update for the Steering Committee

7.2 E-reporting codings
It was reported that the ISO "event codes" Technical Specifications document is now completed (ISO TS 19218-1). Publication is expected early 2011. The same ISO TC 210 committee will now focus on the "evaluation codes" (ISO TS 19128-2).
This is a joint activity with FDA and SG2. The ISO codes will be restricted to a 2-level nomenclature, aligned on the high level codes being prepared by FDA. Comments are

solicited from SG2 members on this part 2.

- Actions
  - Circulate draft version of the evaluation codes along with questions on specifications of the future 19218-2 for TC210
  - Comments from members to be transferred to ISO TC210

7.3 New Work item: Proposal to harmonize Adverse Event Codes.

The Japanese delegation proposed this NWI. The proposed Work Item extends beyond the ISO codes (proposal for harmonization). Some suggestion of wording made. Yokoi-san presented the existing Japanese coding terms nomenclature. It was decided to map the various codes via an inventory of potentially "harmonizable" codes and review the work item at the next meeting.

- Actions:
  - Modified version of proposed NWI to be circulated
  - Yokoi-san to start the codes inventory and to report at next meeting for possible decision on follow up action ..

7.4 Proposed revision of ISO 13485

Requests on the SG2 opinion on a possible revision of the quality standard ISO 13485 has been received from the GHTF SC. Also received was a call for participation to an ISO TC210 ad hoc group focusing on Post Market Surveillance. The Chair took the action to clarify these requests in view of formulating SG2 position.

- Actions
  - Organize teleconference with E. Cobbold and M. Olhson to clarify the proposal and relevance of this activity to SG2
  - SG2 to decide on representative in this ISO TC 210 Task Force and overall position

8. SG2-SG5 -Adverse Events reporting during clinical investigations

An update was given by the ad hoc sub group on the Brussels joint SG2-SG5 meeting and follow up conference call. The resulting document was reviewed and changes recorded.

Suggested modifications were made in the introduction to clarify the transition regime following regulatory approval of a device under study. Reporting criteria were clarified under 7.2. Addition of age and year of birth was proposed under 8.0 and a new suggested flow chart was introduced in Fig 1.

- Actions:
  - Consolidate the group comments, including the lay out of Figure 1
  - Distribute consolidated document to the Vice Chair of SG5 for review.

9. NCAR Exchange Program

The NCAR secretariat presented the updated report.

When N111 will be finalised, it is proposed to modify the NCAR form to align action on corrective actions on the N111 definitions.
Request from outside organization on the NCAR statistics. SG2 position is that the updated set of slides circulated to SG2 is confidential and cannot be shared outside of the group as it contains sensitive and proprietary information. A smaller version will be elaborated for external use.
ID informed the group that the application from Taiwan has been approved by the Steering Committee. Japan MHLW/PMDA will be the lead trainer Authority, assisted by Australia TGA. The draft N120 document (on training for PMS, incl. the NCAR Exchange Programme) will be tested during this training.

- Action:
  - Prepare an NCAR presentation that can be used externally

10. Document on training N 120

Document N120R4 on Training for Post Market Surveillance was reviewed and comments collected.
AHWP made a request to have extracts of the DVD prepared by SG2 in Gaithersburg posted on its web site. The group agreed to have the N54 section of the DVD posted (not the NCAR training presentations) and asked AHWP to add a disclaimer stating that this is an initial tool posted for general education purpose only.

- Actions:
  - Document N120 (now N120R5) – final document to be reviewed by the Chair for presentation to the steering committee
  - TGA to circulate its assessment program on "managing NCAR reports" to NCA members

11. Review of existing SG2 Guidance

Defered to next meeting

12. SG2 contribution to other GHTF documents.

The Chair reviewed other study group documents and solicited comments from SG2 members.
SG3 PDN18R8 / SG1N22R71 / AHWG SC PD N2R1 Member interest subgroups have been allocated for documents.

- Actions
  - SG3 PD N18R8 to be re-circulated for comments to sub group
  - AHWP PD N2R1 (Safety Alert Dissemination System: Criteria, Procedures and Form) to be circulated to the interested sub group when a new version is available.

13 GHTF SG2 - AHWP WG2 liaison

M Tanakasemsub presented an update of the work of AHWP WG2. Highlights:
- Regarding the SADS system and convergence with NCAR, a new manufacturer adverse event reporting form is being developed. While substantially simpler than the SG2 form, it should remain compatible and will expand toward merging with the SG2 form as the program get through its learning curve.

.-WG2 supports member economies who are ready to apply to the NCAR program

- Action:
  - AHWP updated presentation to be circulated.

14. Review of the web site.

Brief discussion only. The revised version of N80 (Slides on PMS Activities) will be discussed at the next meeting.

- Action:
  - Chair to revise the existing work plan format in view of updating the web site

15 Review of actions and work plan

The action item list resulting from the meeting (N118R7) was reviewed with the group. Changes were made based on feedback. The work plan (N49R24) was also updated.

- Action:
  - Work plan and Action list to be circulated to the group

Future SG2 meetings

The Chair suggested to have 2 meetings in 2011, and to make provisions to extend the duration of each meeting to 4 days. This was agreed.
1st 2011 meeting. April 12-15. Australia, hosted by TGA in Canberra – to be confirmed
2nd 2011 meeting. Joint meeting with AHWP. Date and place to be agreed.

I Demade closed the meeting, recognizing all participants' engagement and positive input.

Many thanks for GE Healthcare Freiburg for the excellent organization of the meeting

End of minutes (P Auclair / I Demade)