



GHTF SG2- 39th Meeting
Location: St Jude medical
15900 Valley View Court Sylmar , CA 91342
Date: February 23-25th , 2010

Attendance:

Name	Organization	Email	23/02	24/02	25/02
Takehiko Arima	JFMDA	tarima@its.inj.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
Hiroshi Ishikawa (HI)	JFMDA	hiroshi4.ishikawa@toshiba.co.jp	X	X	X
Barbara Mills	MITA	Barbara.Mills@ge.com	X	X	X
Carmen Ruiz Villar (CRV)	AEMPS Spain	cruizv@aemps.es	X	X	X
Yoshihiko Sano	MHLW	sano-yoshihiko@mhlw.go.jp	X	X	X
Michael Santalucia	AdvaMed	'Michael.Santalucia@bausch.com'		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@bausch.com	X	X	X
Hiroyuki Tanishiro (HT)	PMDA	tanishiro-hiroyuki@pmda.go.jp	X		
Expert(non member)					
Ben Khosravi (BK)	St Jude Medical (SJM)	bkhosravi@sjm.com	X	X	X
Observers					
Greg LeBlanc (by tel)	SG5 liaison	gregleblanc@cookcanada.com		X	
Yuka Sugamura (YS)	PMDA	Sugamura-yuka@pmda.go.jp	X	X	X
Hideto Yokoi	MHLW	yokoi@med.kagawa-u.ac.jp	X	X	X
Members-Not attended					
Carl Wallroth (CW)	EUROM VI	beate.moeller@draeger.com			

Welcome, Introductions, Announcements

Day 1 of the **39th meeting of GHTF Study Group 2** began at 11:00 AM on February 23rd 2010, with a greeting from the Chair, **Dr. Isabelle Demade**, (EU Commission) extending thanks Ben Khosravi (SJM) for hosting the meeting.

Review meeting agenda

The agenda was adopted, with appropriate modification allowing G Leblanc (SG5) to join by phone on Day 2 to participate to agenda item 9. (Adverse Event reporting during Clinical Investigations).

I Demade made an update on the membership. M Santalucia is the new Advamed representative. B Khosravi has kindly accepted to participate as an external advisor/expert until completion of the two draft guidance under development, NWI “Definition and Classification of Field Safety Corrective Actions, including recalls” and “Adverse events during clinical investigations”, on which experience and knowledge will be greatly appreciated.


The Chair noted that C Wallroth (EUROM VI) did not participate in any of the last 3 meetings and suggested to have his name deleted from the SG2 list of participants. Y Sugamura (PMDA) attended the meeting as an observer.

I Demade presented the 2009 SG2 achievements:

- Adoption of the revised guidance N79 and N 38
- Finalization of the 1st implementation phase of PD N87, i.e. completion of the EU pilot project on electronic transfer of adverse event data-sets by MFRs to NCAs.
- Start of two new Work Items:
 - > “Definition of Field Safety Corrective actions, including recalls “
 - > “Adverse event reporting during clinical investigations”
- Cooperation and liaison with AHWP WG2.
- Training activities:
 - > training of new NCAR participant : Thailand FDA;
 - > training of Chinese SFDA through US FDA
 - > draft document on NCAR training
 - > updated of training log

Minutes from the previous SG2 meeting

The minutes from the Hong Kong Nov. 2009 meeting were approved (document N121), with modification on the spelling of the Spanish Agency (AEMPS) and a correction on typos.

-  Action :
- modify the minutes and request posting of N121 on the GHTF SG2 web site
 - revise the members list and the email distribution list as agreed

Review of the actions items from the last meeting

Action items from the previous SG2 meeting were reviewed. The Chair noted the excellent progress.

Report on GHTF Steering Committee Activities. (I. D)

I Demade reported on the latest SC teleconferences highlights:

- Completion of the Memorandum of Understanding between GHTF and ISO

- New GHTF Chair: L Kelly (TGA)
- Next important dates:
 - Steering Committee meetings. 9-11 May in Singapore / 2-4 November in Sydney
- Finalization of the work of the AHWG on combination devices whose objective was to present a clear picture of the various regulatory agencies' approach to combination devices and of the possibility for harmonization. The issue will now be discussed at the Heads of Agencies meeting.
- Proposed GHTF AHWG Discussion Paper on UDI; (SG2 comments solicited).
- Proposed GHTF SG3 guidance on corrective action and preventive action and QMS processes. (SG2 comments solicited).
- SG1 Report on initiated contact with HL7 for e- submission

N111 - Definition and classification of Field Safety Corrective Actions (FSCAs), including recalls – PC and team

1. Definitions

The revised definitions and examples of the sub group (PC lead/MB/BH/BM/Miang/Arima-san) were discussed in detail, reviewed and commented. The group reached agreement on the 5 types of FSCAs and 3 types on non FSCAs. Examples were reviewed and modified.

A new working draft N 111 R4 was prepared during the meeting. The definitions part of the document is now mature; to be finalized at the next meeting.

Action :

- Add in the Introduction wording on GHTF goals and on differentiation between this guidance and requirements for premarket product modifications (CAPA)
- Pull out Appendices 1&2 (Status document on def. and classification in the different GHTF jurisdictions) from the draft guidance
 - Comments on the new document
- Compile comments into a new document for next meeting. **Only non resolved / critical comments to be considered.**

2. Classification

Extensive review and comments on the status document and first working draft. Preliminary discussion of the draft. Changes suggested.

Discussion on how to best integrate the probability and severity of health consequences as criteria for classification.

Reference to be made to SG3 N15R8:2005 on risk management principles.

Suggestion to review implications of FSCA classification on GHTF SG2 N57R8 (content of FSN).

Action :

- Document output from the meeting to be circulated
- Task Force to refine classification criteria for class 1; 2 + 3 and to consider stratification inside class 1

SG2-SG5 -Adverse Events reporting during clinical investigations

G Leblanc (MEDEC, SG5 Vice-Chair) participated by phone as SG5 liaison.

P Auclair reported on the outcome of the GHTF SG5 meeting to which he took part as SG2 representative.

The document output of this meeting was reviewed and discussed. All incorporated comments to be forwarded to SG5. A joint SG2-SG5 meeting will take place on June 3-4, 2010 (SG2 Participants: BK/ES/ID/BH/MB/PC/PA)

 Action :

- (1) P Auclair to circulate the revised working document annotated by SG2 (cc: SG5)
- (2) To be considered and discussed with SG5:
development of a reporting format and electronic reporting form.

Nomenclature and ISO TC 210 WG3 progress report

P Auclair reported on behalf of L Hansel, Chair ISO 198 TC215

○ Part 1

Event type codes- Review and comments from the SG2 on the document ISO DTS 19218-1 are welcome.

 Action :

- Comments on Part 1 to L Hansel by the next meeting

○ Part 2-

Evaluation codes- M Brady updated the group with the FDA progress and circulated a draft for possible SG2 comments.

ISO will review the first FDA draft mid 2010.

 Action :

- Comments to be sent to M Brady by the next meeting

SG2 PD N87 on XML Schema for the electronic transfer of adverse event data between manufacturers and NCAs.)

E. Stosslein presented the EU electronic reporting form and answered questions from participants. The form will become mandatory as of March 21, 2010 for manufacturers reporting in Germany. Transmission of reports from MFRs to NCAs is done via email. Other EU Member States are considering adoption. The reporting form and NCAs Vigilance Contact Points are published on the EU Commission website.

Round table on possible adoption by other jurisdictions. Australia is interested and will consider the option/ AHWP WG2 will review the document / Health Canada will review the electronic form with their Information service department / Japan has a local form already available electronically / US FDA has an e-MDR system in place.

E Stosslein presented a mapping of the form content with HL7 tagging. (ICSR map)

 Action :

- The Individual Case Safety Report (ICSR) map to be distributed to SG2 and commented by all for identification of missing HL7 tags and on EU & FDA specificities
- Contact ISO TC 215 to have SG2 rep in appropriate WG
- Work with ISO TC 215 to work with HL7 to include the missing codes

GHTF SG2 - AHWP WG02 liaison

M Tanakasemsub presented an update of the work of AHWP WG2. Update on the SADS system.

Currently 3 AHWP members are participating in the GHTF SG2 NCAR Exchange Program (Saudi Arabia / Hong Kong / Thailand).

Agreement on the proposal to invite an AHWP WG2 regulator representative at SG2 meetings and vice versa. (next AHWP meeting WG2 in Singapore on May 12).

AHWP will consider adoption of the proposed **XML Schema for the electronic transfer of adverse event data.**

The AHWP WG2 action plan is:

- progress in adoption on harmonized regulations
- Simplify the SADS reporting form
- Review with AHWP member economies the FSCA definitions from N111
- Study technical feasibility to use e- reporting
- Define training needs with the member economies

 Action :

- Circulate for comments the AHWP SADS simplified reporting form
- WG2 to formally nominate a WG2 Regulator Representative to SG2
- Establish permanent liaison SG2-AHWP

SG2 Trainings

Update on the training in China by US FDA (abbreviated training on N8/N54/N79.)

Discussion about future needs, especially for AHWP member economies. (use of GHTF training DVD / possible need to develop Q&A / case studies)

Review of NCAR training document drafted by Mary and her team (N120 R3). Group discussion. Need to include forms for assessment of knowledge gained and evaluation of trainers.

- ✚ Action :
- Propose new work item to the SC for N120
 - Finalize N120 in view of adoption as a PD

Review of documents N8/N79

The groups agrees that a review of N8 ("How to Handle Information Concerning Vigilance Reporting Related to Medical Devices") is needed.

A gap assessment of N8 vs. N79 content was presented by H Ishikawa. Discussion about the possible merge of the two documents.

- ✚ Action :
- Comments required on H Ishikawa's presentation, review gaps and propose changes to N79 for the next meeting

Update on "Précis" N12

N12 in its current format is obsolete. There is an overlap between N12 and N16 on Charge and Mission statement.

H Ishikawa presented a tabular comparison of N12 vs. N16. Recommendation is to create an updated "Mission Statement" (N12 R11) and to archive N16. A draft new document (N123 working draft) was produced during the meeting.

- ✚ Action :
- SG2 to review and comment draft working document N123. Comments to Mary Brady by the next meeting
 - N123 to be placed on the agenda for the next SG2 meeting for tentative endorsement.

National Competent Authorities Reports (NCARs)

Note: a Regulator only Session was held before the plenary.

P Carter presented the update NCAR statistics. The group noted a downwards trend in circulating NCARs marked "confidential". The overall number of NCARs exchanged via the Programme remains stable. Discussion about the relevance of this trend and impact for the system took place. An interest to single out adverse event report linked to medical devices used in pediatric was recommended.

Opportunity for SG2 comments on GHTF PDs

Discussion on GHTF proposed documents under public consultation and their impact and relevance for SG2:

- SG3 PD N18R8-(Guidance on corrective and preventive action and related QMS processes)
Discussion on possible impact on SG2. To be further defined.

- AHWG Discussion Paper on Unique Device Identifier for medical devices.
Discussion on possible impact on SG2, especially with respect to product traceability and recall/FSCA effectiveness.

✚ Action :

- SG3 PD N18R8:

Industry trade association representatives to review the two Industry papers.
SG2 relevant comments to be circulated to SG2 members ,if any

- UDI:

Draft SG2 comment to be elaborated by ad hoc group by 26 March. Chair to compile comments and prepare final version, if relevant. Deadline: 31 March. .

Review of actions and work plan

✚ Action:

- P Auclair / I Demade to review and circulate N49 Work plan
- circulate detailed Actions items N 118 R5

Future SG2 meetings

It is proposed to hold the next meeting in Freiburg, Germany on September 14, 15 &16, 2010

✚ Action :

- GE Health Care German Branch to consider hosting the meeting

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

Many thanks for Ben Khosravi (SJM) for the excellent organization and friendly atmosphere of the meeting

End of minutes (P Auclair / I Demade)