GHTF SG2- 41st Meeting minutes

Location: Ministry of Health, Social Policy and Equality, Paseo del Prado 18, Madrid, Spain

Attendance:

Name	Organization	Email	30/05	31/05	01/06
Takehiko Arima (TA)	JFMDA	tarima@its.jnj.com	X	X	
Philippe Auclair (PA)	EUCOMED	philippe.auclair@av.abbott.com	X	X	X
Mary Brady (MB)	FDA	Mary.Brady@fda.hhs.gov	X	X	X
Pam Carter (PC)	TGA	Pamela.Carter@tga.gov.au	X	X	X
Isabelle Demade (ID)	Eur. Commission	isabelle.demade@ec.europa.eu	X	X	X
Hiroshi Ishikawa (HI)	JFMDA	hiroshi4.ishikawa@toshiba.co.jp	X	X	X
Bertram Koening (BK)	EUROM VI	bertram.koenig@bbraun.com			X
Barbara Mills (BM)	MITA	Barbara.Mills@ge.com	X	X	X
Carmen Ruiz Villar (CRV)	AEMPS Spain	cruizv@aemps.es	X	X	X
Christopher Rose	Health Canada	rose@hc-sc.gc.ca	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
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) by phone part of the meeting	BfArM	e.stoesslein@bfarm.de	X	X	
Observers					
Yutaka Matsui (YT)	PMDA	matsui-yutaka@pmda.go.jp	X	X	X
Hideto Yokoi (HY)	University expert	yokoi@med.kagawa-u.ac.jp	X	X	X
Members-excused					
Tanaka Daisuke (TD)	MHLW	Tanaka-daisuketd@mhlw.go.jp			
Yuuta Maeda (YM)	MHLW	maeda-yuuta@mhlw.go.jp			
Essam Mohammed AlMohandis (EM)	Sector Saudi Food and Drug Authority	EMMohandis@sfda.gov.sa			

1. Welcome, Introductions, Announcements

Day 1 of the **41st meeting of GHTF Study Group 2** began at 11:00 AM on May 30th, 2011 with a greeting from Mrs Carmen Abad- Luna from AEMPS Spain, giving overview of the AEMPS and wishing the group a good working session. She also expressed her interest and support to international harmonization of AE reporting and recognized the good work done by the GHTF SG2.

The Chair, **Dr. Isabelle Demade**, (EU Commission) extended thanks to AEMPS for hosting the meeting. She expressed her apologies for the cancellation of the Canberra meeting, previously scheduled in April 2011. She also announced that her term as a Chair was coming to an end in December 2011. In view of the projected closure of the Study Groups by the end of 2012, she offered to remain Chair until the group closure. This was unanimously approved.

Christopher Rose introduced himself as Health Canada representative, in replacement of Barbara Harrison, and was welcomed by the group.

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

The draft agenda was adopted

Minutes from the Freiburg meeting were approved (document N124) with modification of M. Santaluccia's email address and correction on typos.

Actions :

- Final minutes Freiburg N124. PA to distribute final version and ask 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 progresses and placed emphasis on the major work items:

- N111 (Definition and classification of Field Safety Corrective Actions -FSCA- , including recalls)
- Finalization of N87 (electronic transfer of AE between manufacturers and NCAs)
- SG2 input as ISO liaison for the possible revision of ISO13485 (incl. Post market surveillance section)

4. Report on GHTF Steering Committee Activities.

I Demade reported on the latest SC teleconferences highlights:

4.1 Future GHTF organization (as presented by L. Kelly at the steering Committee)

Membership will be extended to new countries. Invitations to join will be sent to Brazil, India, China and Russia (the "BRIC" countries).

Strategy will be defined by a regulator-led committee supported by ad-hoc working-groups. Input from Industry will continue to be vital. Input from other stakeholders such as healthcare professional groups, academia and consumers will be welcome.

As a result, the study groups are asked to close their open Work Items by December 2012. The National Competent Authorities Reports (NCAR) Exchange Program will be maintained.

Discussion took place on the new proposed governance of GHTF and implications for SG2.

Action:

 Prepare statement from SG2 to Steering Committee to contribute proactively to the new GHTF structure and alert the Steering Committee on SG2 concerns.

Lead BM. With Miang / CR/ID/MB/PA.

Timeline: to be ready end July 2011 for the next steering committee conference call.

4.2 Regulatory Model document N1 **R13:2011** was approved by the Steering Committee as final. SG2 proposals are included.

Action:

Some typos to be corrected.

MB lead – Done at the meeting. To be transferred to the Steering Committee by HI.

4.3 SG2 N120 R7: 2011 - Training document

The document was endorsed as a working internal SG2 document. It will not be posted on the web site.

Actions

- N 120: PA to include the changes agreed at the meeting and send it to ID/MB. The document dated June 2011 is considered as final.
- N115: HI to inform PA on the Taiwan NCAR training session. PA to update N115 and transfer to the NCAR secretariat for maintenance.
- List of approved trainers: MB to circulate the list, all to comment. List to be transferred to the NCAR secretariat for maintenance.
- Review of all available training materials– PA /ID. ID to prepare a template training slide-deck and transfer to the NCAR secretariat for maintenance

4.4 SG5-SG2 N5 R9:2011: Adverse Event reporting clinicals

The document was approved as a PD by the Steering Committee for a 6 month consultation period.

Action:

SG2 members to send comment by end August 2011 to PA and ES.
PA to consolidate SG2 comments and circulate consolidated SG2 contribution to all.
Finalization at next SG2 meeting

5. GHTF SG2 N87 -An XML Schema for the electronic transfer of adverse event data between manufacturers, authorized representatives and National Competent Authorities**.**

The Steering Committee requested an update on the document.
Discussion on the alignment of the xml codes from N87 and HL7. Some fields cannot be mapped as HL7 codes are missing 5 to 10 fields. A conversion tool may be required to ensure compatibility. This would require additional IT resources. SG2 does not see this activity in its remit.
The N87 xml were tested in several GHTF member countries. The pilot was successful. The N87 XML scheme is now in use in some GHTF members.
SG2 considers N87 pilot program as completed. SG2 recommends using the xml scheme in new countries adopting electronic reporting.

Actions:

- ES to finalize N87 by including the xml codes in appendix.
- ID to table final N87 at the Q1 2012 Steering Committee for approval.

6. N111 R6 working document - Definition and classification of Field Safety Corrective Actions (FSCAs), including recalls.

PC presented the working document N111 R6 as prepared for the meeting.
The group reviewed the introduction and definition of FSCAs. It was decided to replace “non FSCA” by “non safety-related field corrective actions” in the document as appropriate.
The whole document was reviewed and commented .Definitions are finalized.

Section 7 on classification of FSCA was discussed in depth and modified. Comments from various SG2 members were presented. The section was reorganized as classification of Field Corrective Actions (FCA). Specific requirements in jurisdictions were considered. Introduction on section 7 was re-written.

Actions :
- PA to distribute N111 R7 as reviewed (tracked and cleaned version)
- Work on examples for section 7 -MS/ Miang
- PC -lead- to organize a conf call(s) to finalize the document.
- Final document to be proposed to the next Steering Committee

7. Possible revision of GHTF/SG2/N57R8:2006- Content of Field Safety Notices

Discussion on possible alignment of the existing N57 with the new definition given in N111 R7- working document. The group recommendation is to make an editorial change to the definition of FSCA in N57 to match N111. To be done at the time of approval of N111.

Action:
ID to prepare a plan for approval by the Steering Committee.

8. Standardization activities

8.1 Update on ISO 19218-2 evaluation codes

PA tabled a written update on the behalf of the Technical Committee (TC) 19218 group Chair , L. Hansel. The next meeting of the TC will be on June 14-15. Best possible timeline is to have a vote on the Technical Specifications (TS) in October 2011 to allow a publication in 2012.

Action :
Comments on draft TS 19218-2 to be sent to MB/PA before the next TC meeting

8.2 Harmonization of Adverse Events codes

HY presented an inventory of existing codes for event codes, cause codes , patients codes. Presentation on SNOMED -CT and discussion on the possible use of MedRA codes.
The group noted that the work on harmonization of all codes for reporting events needs to be pursued, even if this will not be compatible with the expected SG2 closure in end 2012.

Action:
PA to circulate Japan presentations to the group

8. 3. Proposed revision of ISO 13485

An ad hoc meeting of a ISO 13485 task force was held in April in Malvern , USA. From SG2 , HI/EM/ID attended. Possible changes to the standard may include Complaint handling, Post Market Surveillance, Adverse Events reporting in the pre-market clinical phase.
Should the revision of ISO13485 proceeds, the group recommends SG2 participation to the revision of the standard.
Rationale: SG2 members knowledge and experience in PMS-related activities. SG2 guidance to be considered. Avoid overlap and duplication.

Actions
Creation of an ad-hoc TF to contribute to TC210 WG- ID-lead with CR/MB/HI/EM/MS/PA to contribute to preparation and be available for conf calls & meetings

9. NCAR Exchange Program

These issues were discussed during an Authorities closed door meeting and reported at the general meeting.

9.1 Open Items

⇨ Country applications: no new application.

Following the training of the Taiwan Authorities and the recommendation of the Japan NCA, the SC approved the application of the Taiwanese Authority at its Nov. 2010 meeting. The Exchange Program now has 28 NCAs and the EU Commission.

Difficulties were reported on the full understanding of the reporting criteria and the need for case studies.

Action:
- PC to create and to send to Japan trainers and Taiwan CAs "5-10 best report cases".
- "Best case studies" to be used as appropriate to update/develop competencies of existing members of the Exchange Program.

⇨ NCAR 2010 stats- PC presented

The NCAR secretariat presented an updated report.

Comments from Japan on the confidentiality of FSCAs posted on public website (what is the added value to circulate an NCAR after the corresponding FSCA is published on the web?), different meaning of Recalls and FSCAs among Authorities , and need to modify the NCAR reporting form when N111 is adopted

Action:
- PA to distribute the NCAR stats to the group – Should be considered confidential, NOT for circulation outside SG2 members. A version for public information will be distributed later.

9.2 Public data on the NCAR Exchange Program

⇨ The group proposes to have a specific section of the GHTF website on the NCAR Exchange Program. It would include introduction on the program, list of participants, public statistics.

Action:
- Proposal to SC to have a specific section on Steering Committee

⇨ Presentation by PC of the NCAR stats for public release (abbreviated version).

Concerns discussed about use by media

Action:
- PC to update the existing NCAR Public Presentation to include all 2010 data.
- PA to circulate to the group of the abbreviated updated NCAR public presentation

9.3 Mentoring of new members

The objective is to stimulate active participation of new members to the NCAR Exchange Program by an active mentoring.

The group discussed the use of follow-up sessions (and possible retraining), of conference calls to make regular refresher for countries who are not actively participating to the Exchange Program. .

The ASEAN and AHWP meetings are also an opportunity to train/inform on the Exchange Program.

9.4 GHTF-SG2-N8R4:1999

-Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Device- Possible revision
N8R4 is obsolete. Discussion on the best way to update it. Proposal is to archive N8 and to have N8 page 5 on communication of adverse event and related information annexed to N111 when the latter is released, Underlying assumption: N 111 scope is extended to FSN content and communication.

Actions:
- All to consider whether part of N8 (page 5) on "dissemination reports "should remain as an appendix of N111 - for next meeting
- Proposal to archive N8 – to be discussed at the next meeting

10. AHWP TC WG2 update

Miang presented an update on AHWP WG2 and indicated a new WG2 Chair – Yorkie Chow from Hong Kong has replaced Mark Lau who moved to a new position.
WG2 projects include harmonizing the AE reporting form, proposing an electronic reporting format, harmonizing the FSCA form within AHWP and progressing toward a merge of the non confidential part of GHTF NCAR with the AHWP SADS.
Good progresses noted in implementation of N54 among AHWP members.
The next AHWP TC meeting and WG2 meeting will be held in Korea, in July 2011. An APEC training meeting will be organized on that occasion.

Questions were raised as to the future relation with AHWP under the future GHTF model.

Actions
- Miang to send PA/ID the agenda or the AHWP TC meeting and of the APEC meeting.
- ID to consider possible SG2 participation

11. Review of the Steering Committee document on UDI .
A road map on next step for implementation and database decision will be presented to the next SC (expected completion date: end 2012).

Discussion about a possible next step to align with HL7 and creation of an implementation team.

12. Review of existing SG2 Guidance

12.1 Revised mission statement. N123
The group complimented MB/HI for their work . It was decided not to pursue the modification in view of the closure of SG2 by the end of 2012

Action:
The group to consider for the next meeting a parking lot of non approved draft to ensure institutional memory of SG2 is maintained after its closure

12.2 Presentation of SG2 documents and PMS activities: N80.
Revised document N80R9 was reviewed and approved with minor changes.

Actions:

- ID to propose the revised version of N80 (R9) for endorsement at the next SC teleconference
- PA to request posting on the web-site as replacement of the old N80 when agreed

15 Review of actions and work plan

The action item list resulting from the meeting (N118R8) was reviewed with the group. Changes were made based on feedback. Document finalized and circulated

Action:

- ID to update Work plan and circulate to the group

Future SG2 meetings

Following TGA proposal, the Chair suggested to hold the **next meeting on November 7th -10th 2011 in Canberra (Australia) ,** hosted by TGA.
Morning of the Monday 7 as a closed door meeting for Authorities, main meeting on 7th afternoon, 8th , 9th and 10th until mid day. This was agreed by the group.

The Chair of SG2, I Demade, closed the meeting, recognizing all participants' engagement, positive input and thanking AEMPS for the excellent organization of the meeting

End of minutes (P Auclair / I Demade)