



GHTF SG2 Meeting
Location: Westin Harbour Hotel, Toronto
Date: 10-12 May, 2009

Attendance:

| Name | Organization | Email | 10/05 | 11/05 | 12/05 |
|--------------------------------|---------------|--|-------|-------|-------|
| Isabelle Demade (ID) | EC | isabelle.demade@ec.europa.eu | 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 |
| Ben Khosravi (BK) | AdvaMed | bkhosravi@sjm.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 |
| Barbara Mills | MITA | Barbara.Mills@ge.com | X | X | X |
| Carmen Ruiz Villar | AGEMED Spain | cruizv@agemed.es | X | X | X |
| Barbara Harrison (BH) | Health Canada | barbara_harrison@hc-sc.gc.ca | X | X | X |
| Members-Not attended | | | | | |
| Takehiko Arima | JFMDA | tarima@its.jnj.com | | | |
| Hiroyuki Tamishiro (HT) | PMDA | tanishiro-hiroyuki@pmda.go.jp | | | |
| Yoshihiko Sano ("Yoshi") | MHLW | sano-yoshihiko@mhlw.go.jp | | | |
| Jorge Garcia (JG) | TGA | jorge.garcia@tga.gov.au | | | |
| Hiroshi Ishikawa (HI) | JFMDA | hiroshi4.ishikawa@toshiba.co.jp | | | |
| Carl Wallroth (CW) | EUROM VI | beate.moeller@draeger.com | | | |
| Observers / visitors | | | | | |
| Dulce Maria Martinez | CCEEM Cuba | dulce@cceem.sld.cu | X | X | X |
| Pereira | | dulcema@infomed.sld.cu | | | |
| Kevin Chin | Health Canada | Kevin_Chin@hc-sc.gc.ca | | X | X |
| Mark Bailey | Health Canada | Mark_Bailey@hc-sc.gc.ca | | X | X |
| SG Liaison-ad hoc group | | | | | |
| G. LeBlanc | SG5 liaison | gregleblanc@cookcanada.com | X | | |
| S. Ludgate | SG5 liaison | Susanne.Ludgate@mhra.gsi.gov.uk | X | | |
| C. Bailleul | SG5 Liaison | CBailleul@SJM.com | X | | |

DAY 1: MAY 10, 2009

Welcome, Introductions, Announcements

Day 1 of the 37th meeting of GHTF Study Group 2 began at 9:00 AM on May 10, with a greeting from B. Harrison (Health Canada) and K.Stitz (MEDEC) hosting the meeting. The Chair, **Mrs. Isabelle Demade**, (DG Enterprise and Industry) relayed apologies for the absence of the Japanese delegation. It was agreed to give the Japanese SG2 members 2 weeks to review and comment on meeting decisions and recommendations.

Mrs. Carmen Ruiz, AGEMES Spain, is accepted as a full group member, representing European regulators.

The group noted the replacement of J. Garcia (former Chair SG2) by Mrs. Pamela Carter (TGA), and expressed its recognition to Jorge for his contribution to the group as a Chair and trainer.

Mrs. Dulce Maria Martinez, CCEEM Cuba, attended the meeting as an observer.

After a group discussion, it was agreed that membership application of medical device consultants was not to be retained, unless the applicant is an expert on specific topic. The decision is being left to the Chair discretion.


The group expressed congratulations to the Chair and Secretariat for the organization, and process of follow up / reminders after the Brussels meeting.

Review meeting agenda

The agenda was adopted, with appropriate modification allowing the Chair to present SG2 Status Report and Work Programme to the GHTF Steering Committee and allowing J. Garcia (TGA) to join by telephone for the N111 discussion.

Minutes from the previous SG2 meeting

Minutes from the last meeting held in Brussels, Belgium were approved. (Document N117).

 Action 1: PA to contact web master for posting N117 on the web site

 Action 2: PA to organize review list members for web site posting

Review of the actions items from the last meeting

Action items from the previous SG2 meeting in Brussels, Belgium were reviewed. The Chair noted the excellent progresses.

The group discussed numbering of documents. It was decided to maintain the current chronological increment of numbering for all controlled papers via an internal document log.

Report on GHTF Steering committee. I. D

ID reported on the 26th February SC teleconference.

Main points of relevance for SG2 were:

definition of combination products.

The Ad Hoc WG (AHWG) has been given an extension to complete their work.

The AHWG asked each of the SG's to provide their assessments of which of their documents would need to be updated or modified or where new documents might be required to accommodate combination products. The overwhelming sentiment of SG Chairs was that it will be very difficult to make a reasonable assessment of the work involved without some clear definitions and some clear guidance as to what exactly is meant by combination products.

- ☐ training activities (J Welsh has taken over as Chair of the AHWG);

The revised N79 and N38 were submitted to the Steering Committee for discussion/tentative endorsement. The documents will be on the agenda of the next Steering Committee teleconference (12 July) for possible approval.

🚩 Action 3: ID to communicate to group dates of Steering Committee teleconferences

➤ **N1R4 AHWG paper on regulatory model -ID**

Concerns were expressed with the presentation of SG2 activities, which is not aligned with the other SG presentations (see section 11.2 of the doc).

🚩 Action 4:

- ID to clarify with T. Ulatowski the timeline for comments
- Modify section 11.2 with a short intro and produce a “spaghetti chart”- reference to PMS precious docs- “Yoshi” lead, with BH/PA/Miang (Miang to provide the “spaghetti software”)

➤ **N111 - Harmonization FSCA / Recall definitions - JG and team**

Was discussed on Day 1 and 3. JG joined by phone during Day 3. The result of the 2 discussion sessions is as follows:

The output definitions of the sub group (JG-lead/MWB/BH/BM/Miang/Arima-san) was reviewed. Definitions were adjusted. As a result, draft definitions for FSCA type 1/2/3/4/5, as well as Non FSCA Type 1, 2 & 3 have been produced.

These definitions were introduced in the mapping document from Brussels.

🚩 Action 5:

- PA to circulate Documents – definitions / table map to the Task Force (PC - lead/MWB/BH/BM/Miang/Arima-san/ID)
- ID to link with Arima-san - not present at the meeting
- Task Force to produce examples for each definition + KS to produce examples for IVDs
- ID to send docs + examples to the whole SG2 members- when ready
- Task Force to refine / finalize terms
- PA to produce a graphical rendition map of the “Universe of FSCAs”

➤ **Ad hoc meeting SG2-SG5 -clinical AE reporting**

SG2 Participants: BK/ES/ID/BH/MWB/PC/PA;

SG5 Participants: S. Ludgate (MHRA,SG5 Chair), G. Leblanc (MEDEC, SG5 vice-chair, C. Bailleul (Eucomed).

Draft document was reviewed and commented. Will be reviewed by SG5. G. Leblanc to produce minutes of the meeting of the ad hoc working group and to organize conf call for the TF. Report at the next SG2 meeting.

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| <u>DAY 2: MAY 11, 2009</u> |
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➤ **Issues related to National Competent Authorities Reports (NCARs) Exchange Programme**

(1) NCAR performance and statistics (PC)

Presentation of the update (up to end March 09). The number of reports labeled “confidential” is going down, but the understanding of the confidentiality concept for NCAR does not seem to be harmonized. When it comes to percentage, Europe is the big driver, UK especially and Ireland being the heavier contributors. In the case of UK, there is most probably a misunderstanding of the reporting criteria. This is being addressed by the UK Authorities. Other major trend: US FDA contribution has significantly declined during the last years, due to internal policy changes that may be revised in the new future.

✚ Action 6, in relation to NCAR stats :

- Finalize the NCAR update, based on comments. PC/PA to distribute
- Circulate updated list of full NCAR participants on a regular basis (PC)
- Include in next NCAR Performance and Stats Report region breakdown – PC

(2) NCAR Exchange Programme TF (MWB): Critical review of performance.

MWB reported on the group output. (BH/ES/“Yoshi”, plus consultation with M. Segstro and D Yoder). A **report on Problems and Issues-Proposed solutions-** was circulated. Main identified problems: understanding of “confidentiality “;usefulness of the form; reduced contribution outside of European countries; need for continuous education.

✚ Action 7, in relation to NCAR performance::

- Prepare as required periodic email “tips and tricks”- PC + regulators
- Critical review of the reporting form - PC – lead (with BH/ES/CR/MWB/“Yoshi”)

- Deep Dive -Review sample of 10-20 reports for producing guide (including confidentiality - PC – lead (with BH/ES/CR/MWB/“Yoshi”)
- Invite NCAR participants from the region where SG2 is meeting. e.g. Asia-ID

A proposal of database for inputting and recording NCARs was proposed by Mrs. M. Dulce from Cuba.

✚ Action 8: PA to circulate the proposal from Cuba

(3) Criteria for trainers in GHFT/SG2 (MWB)

MWB tabled a paper on the above mentioned issue. Joined work with ES. The paper review criteria for general SG2 training, and specific NCAR training for new NCAR participants. There was a general consensus on the document. It was reinforced that group NCAR training was not a substitute for the NCAR “mentoring “/accreditation described in N38.

The need to develop training document for groups of more advanced/experienced participants, including practical case scenarios encountered with the Programme, was acknowledged. This issue requires further discussion/elaboration at NCAR Training TF level.

✚ Action 9:

- Provide feed-back on the document to MWB- All
- Review the proposed document based on feedback – MWB
- Give number – Circulate to the group for review - PA
- Send to J Welsh – AHWG on GHFT training - ID

(4) GHFT SG2 Training (PA)

- N115 - Log of trainings –

PA tabled N115, revised after the Brussels comments. The group decided to supplement the document with the NCAR training for accreditation

✚ Action 10:

NCAR trainers to supplement the document N115 with training for accreditation (S. Arabia – PC/Cuba - BH/Hong Kong - PC) and send to PA

- Core training documents (PA)

✚ Action 11:

PA to circulate the training slides used at the APEC Toronto by ES / PA for further review by SG2 Members .

➤ **SG2 electronic reporting program and ISO work / Nomenclature/ HL7** – Liaison TC 210 / TC 215

(1) Nomenclature and ISO TC 210 WG3 progress report
(PA on behalf of Leighton Hansel-LH)

○ Part 1.

Event type codes -ISO DTS 1921-8 is being reviewed by WG3. High probability of acceptance. The document includes an appendix explaining the mapping with the FDA Codes. The foreseen timeline is to have it released as a TS (Technical Specification) by end of 2009. The document is “99% harmonized with FDA” thanks to the code mapping. EU considers it acceptable for EUDAMED link.

🚩 Action 12:

- PA to ask L. Hansel to change reference from N21 to N54
- PA to request an update on WG3 outcome to L. Hansel and to report to SG2

○ Part 2 and 3

MWB gave progress report on the FDA:

- “Evaluation” codes. Document will be released for comments by Advamed and later forwarded to ISO TC 210 WG3.
- “Methods” and “result / conclusions” codes are being prepared . ISO TC 210 WG3 will process the “result / conclusions” codes , but does not have a plan to include the standard the “methods” codes developed in parallel by FDA. The group agreed.

(2) Health Informatics and ISO TC 215 work :

HL7 Events codes, and compatibility with N87 (ID/ MWB)

ID reported the approval of GHTF SC to go ahead and establish a liaison with ISO TC 215, and presented a document on TC 215 organization obtained from ISO TC 215 Chair, Dr. Kwak. A Memorandum of Understanding (MoU) is being prepared to establish liaison with WG6 – and possibly WG7.

🚩 Action 13:

- ID to prepare MoU to be approved by TC215 and GHTF SC (support MWB and ES)
- ID to name liaison representative for next TC 215 WG7 meeting

AHWP WG02 update- (Miang)

Miang presented a status report of AHWP TC WG2 activities and future projects and the AHWP Status of implementation of SG2 documents (N116 R2), essentially the transposition of N54 in the major AHWP geographies.

✚ Action 14:
PA to circulate AHWP Miang update docs - Presentation and revised N116R2 (Asia harmonization chart)

Pilot program e-reporting N87 (ES)

ES reported on the pilot program which started on Nov 2008. To date 200+ reports have been received in Germany only. (Note: 3 other countries participate). The form follows N87 and the data can be sent via batch XML; or coded acrobat PDF. Germany intends to make this e- reporting mandatory locally on March 2010. After the Pilot is completed in all participant Member States, the EU will consider how and when its database may be adapted to allow this type of data exchange at EU level.

✚ Action 15:- ES to prepare update on EU pilot e-reporting
- PA to circulate the update to the group

Map on SG2 guidance N80 R9 (revised version provided by Jorge Garcia)

The new version produced by JG, including edits recommended in the last meeting was reviewed.

✚ Action 16:
- PA to send the “new” version for web site posting
- PA to request posting of the old version N61R4 on the archive section of the web site
- “Yoshi” to review slide 10 of the “OLD” N80 (Post market activities) and to provide suggestion and rationale for re-introducing slide 10 in a different format in N80 in the near future

N79 R4 (NCAR exchange) & N38R18(Applic criteria.) ID

Documents approved internally after a comment period. Will be tabled at the next Steering Committee Teleconference for endorsement and later posted on the web site.

N8 R4 Guidance on How to Handle Vigilance reporting (ID /PA)

The group recommends revision of N8. The modification may include adoption of additional recommendation for public information on field safety corrective actions to avoid reoccurrence of incidents. The Japanese delegation has recommended to merge N79 & N8-(IH doc). In the absence of the Japanese delegation, this will be discussed at the next meeting.

- ✚ Action 17:
To be placed on the agenda of the next meeting. N8 revision - inclusion of communication to the public? Merge with N79 ?

DAY 3: MAY 12, 2009

N111. Harmonization FSCA / Recall definitions

Review of finalization of action items. For convenience, reported under Day 1. See above.

Ad hoc meeting SG2-SG5 -clinical AE reporting

Review of finalization of action items. For convenience, reported under Day 1. See above

Review of actions and work plan

- N49- **Work plan** was reviewed.

✚ Action 18 : PA to circulate N49 R 21

- N 144- **Actions items** were reviewed and agreed.

✚ Action 19: PA to circulate action items to the group ASAP

Future SG2 meetings

It is proposed to have a joint meeting with AHWP, organized back to back with the AHWP conference, held in Hong Kong in November 2009. November 8-9-10 are proposed (Tentative).

✚ Action 20: Miang to communicate possible dates to ID

ID closed the meeting, recognizing all participants' engagement and positive input. Many thanks for Health Canada and MEDEC for hosting the meeting.