

Final

**GLOBAL COOPERATION GROUP MEETING REPORT
TUESDAY JUNE 09, 2009**

*Yokohama, Japan
(Yokohama Royal Park Hotel)*

Ref: GCG 109F

PARTICIPANTS:

Mr. Kohei Wada	JPMA (GCG Co-Chair)
Mrs. Lenita Lindström-Rossi	EU (GCG Co-Chair)
Mr. Shinobu Uzu	MHLW
Dr. Justina Molzon	FDA
Dr. Alice Till	PhRMA
Dr. André W. Broekmans	EFPIA
Dr. Yves Juillet	EFPIA
Dr. Lembit Rägo	WHO
Mr. Mike Ward	Health Canada
Dr. Petra Dörr	EFTA
Dr. Odette Morin	IFPMA
Dr. Sumol Pavittranon	APEC
Dr. Yuppadee Javroongrit	ASEAN
Prof. Dr. Saleh Bawazir	GCC
Dr. James Fitzgerald	PANDRH
Mr. Joseph Mthetwa	SADC
Dr. Tania Siteie	SADC
Dr. Leonie Hunt	DRA of Australia
Mr. Debasish Panda	DRA of India
Dr. Surinder Singh	DRA of India
Dr. Christina Lim	DRA of Singapore
Dr. Huei-Xin Lou	DRA of Singapore
Dr. Dong Deuk Jang	DRA of South Korea
Ms. Eun Hye Park	DRA of South Korea

Also Present:

Mr. Takayuki Okubo	MHLW
Dr. Kurajiro Kishi	JPMA
Ms. Joan Blair	FDA
Ms. Mary Lou Valdez	FDA
Dr. Michelle Limoli	FDA
Ms. Tammie Bell	FDA
Ms. Mary Morrison	FDA
Dr. Peter Honig	PhRMA
Dr. Michael Garvin	PhRMA
Dr. Thomas Salmonson	EU
Dr. Matus Ferech	EU
Dr. Spiros Vamvakas	EMEA/EU
Dr. Elisa Siviglia	EFPIA
Dr. Lahouari Belgharbi	WHO
Dr. Dawn Ronan	ICH Secretariat
Dr. Sarah Adam	ICH Secretariat

1. Welcoming remarks and adoption of the agenda

The Co-Chairs, Mr. Wada (JPMA) and Ms. Lindström-Rossi (EU) welcomed all participants to the meeting of the ICH Global Cooperation Group (GCG). A special welcome was extended to representatives of the Drug Regulatory Authority (DRA) of India who were participating in the GCG for the first time.

The agenda was adopted without any modification.

2. Review of current membership

The GCG welcomed for the first time Mr. Debadish Panda and Dr. Surinder Singh as representatives of the DRA of India. Dr. Dong Deuk Jang and Ms. Eun Hye Park were introduced as the new representatives of the DRA of South Korea, replacing Dr. Daibyoung Kim and Dr. Kyung Won Jang. Apologies were received from Dr. Ruth Lopert, DRA of Australia, and Dr. Chi-Chou Liao and Prof. Peter Chang, DRA of Chinese Taipei.

Dr. Tania Sitoie from the Republic of Mozambique was welcomed as the second representative of the SADC. Dr. James Fitzgerald (PANDRH) was introduced to the GCG as the new representative of PANDRH replacing Dr. José-Luis Di Fabio.

The GCG noted that the Industry Co-Chairmanship would rotate from Mr. Wada (JPMA) to Dr. Till (PhRMA) following the Yokohama meeting¹.

¹ Post-meeting note: Following the Yokohama meeting, it was confirmed that Dr. Peter Honig (PhRMA) will replace Dr. Alice Till and assume the GCG co-chairmanship.

Dr. Adam (ICH Secretariat) invited the GCG participants to communicate to the ICH Secretariat any current and future changes in GCG membership.

3. Final approval of the report of the GCG teleconference held on April 21, 2009 (Ref: GCG102)

Action/Decision:

- *The GCG approved as final the report of the GCG teleconference held on April 21, 2009.*

4. RHI pre-meeting report

Prof. Bawazir (GCC) reported on the Regional Harmonisation Initiative (RHI) pre-meeting.

The RHIs discussed the need for flexibility due to differences in capacity and needs of the different authorities and regions.

The RHIs discussed the value of developing training programs for ICH Guideline implementation on key ICH topics such as *Quality* and *Good Clinical Practices* (ICH E6, GCP).

Prof. Bawazir also mentioned the importance of the ICH Q7 Guideline (*API for Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients*), highlighting RHIs' interest in sharing information on API inspections outcomes and the opportunity to work together facilitated by sharing a common standard in their regions.

Prof. Bawazir discussed the outcome of webinars organised by the ICH Secretariat on *Step 2 / Step 4* Guidelines and how to improve current organisation to facilitate the participation of individual countries from RHIs.

5. Regulators Forum report

Mr. Okubo (MHLW) reported on the third ICH Regulators Forum held on June 8, 2009 in Yokohama. The Forum welcomed for the first time the representatives of the DRA of India. India's participation to the Regulators Forum came in addition to that of regulators from the DRAs of Australia, Korea and Singapore, the RHIs of the APEC, ASEAN, GCC, PANDRH and SADC, and regulators from EU, Japan, USA, Canada, EFTA and WHO.

The GCG noted that at the Regulators Forum, the DRA of Singapore provided an update on the ICH Guideline implementation process in Singapore, while APEC and Canada both shared their training experience in their respective regions.

The Regulators discussed the need for establishing a contact list of experts on the ICH Q7, E2C (*Periodic Safety Update Report*) and E6 Guidelines and considered the value of establishing a discussion group to assess key issues on GCP and PSUR.

6. Webinars on Step 2 / Step 4 Guidelines

Dr. Adam (ICH Secretariat) reported on the organisation of the webinars on the *S9 Step 2 - Nonclinical Evaluation for Anticancer Pharmaceuticals* and *Q8(R1) Step 4 - Pharmaceutical Development* Guidelines that were held on February 10 and May 18, 2009, respectively. Participants of the webinars noted the usefulness of the web-conferencing system and appreciated the opportunity to have their questions answered by the Rapporteur. Dr. Javroongrit (ASEAN) highlighted the interest of ASEAN to have more participants from Southeast Asian regions. At their last meeting on June 28-29, 2009 in Manila, Philippines, the ASEAN Pharmaceutical Product Working Group (ASEAN PPWG) recommended the establishment of regional delegations where each lead country will be focussing on a set of specific ICH topics. The ICH

Secretariat will also consider in the future how to exploit the Voice over Internet Protocol communication technology (VoIP).

The GCG supported the development of a signing sheet to be informed on the number of participants to each webinar.

Actions/Decisions:

- *The ICH Secretariat will investigate the use of the VoIP technology;*
- *The GCG supported the development of a signing sheet to assess the number of participants;*
- *The RHIs and DRAs were invited to propose other Step 2 / Step 4 ICH Guidelines on which they would like webinars to be organized.*

7. Comments on Step 2 Guidelines

The GCG noted that no comments had been received from the RHIs and DRAs on the following Step 2 Guidelines: S9: *Non-clinical Evaluation for Anticancer Pharmaceuticals*; Q4B Annex 6: *Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Uniformity of Dosage Units General Chapter*; Q4B Annex 7: *Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Dissolution Test General Chapter*; Q4B Annex 8: *Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Sterility Test General Chapter*. The deadline for sending comments to the Secretariat was by the end of March 2009.

8. WHO Stability Guideline

Dr. Rågo (WHO) reported that the WHO Stability Guideline was finalized and adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations during its meeting in Geneva on October 13-17, 2008 and was presented at the WHO Executive Board meeting in May 2009. The Guideline contains an Annex with data from WHO Member States on stability requirements. It was noted that information for some Member states still needs to be confirmed but would not delay the publication of the Guideline on the WHO website. The annex to the Stability Guideline would be updated as new information will become available.

Action/Decision:

- *The ICH Secretariat will provide a link to the WHO Stability Guideline on the ICH website.*

9. Finalization of RHI Profiles

The GCG noted the publication on the ICH public website on March 6, 2009 of the RHIs profiles for ASEAN, GCC and PANDRH. The GCG also noted the value of the profiles in providing information on structure, harmonisation process and topics under harmonisation in the respective regions.

Mr. Mthetwa (SADC) informed the GCG on the progress made towards finalization of the SADC profile.

Dr. Pavitranon (APEC) and Mr. Ward (Health Canada) highlighted the complexity of the APEC organisation and informed the GCG that the APEC profile was under development.

Actions/Decisions:

- *The ICH Secretariat will follow-up with APEC and SADC for the finalization of their regional profiles;*
- *The RHIs will inform the ICH Secretariat of any changes in their regional profiles in order to maintain the GCG public website up-to-date.*

10. Training and Capacity building

❖ *Feedback from GCG-endorsed workshops* ***China Quality Workshop***

Mr. Ward (Health Canada) provided an update on the outcome of the Quality workshop that was held in Beijing, China on December 3-5, 2008 which focused on the implementation of the ICH Q1-Q7 Guidelines in addition to the Q8, Q9, Q10 and Q11 Guidelines. The event was well received and welcomed over 200 participants from across China from Regulatory Agencies and Industry.

APEC LSIF Workshops: Review of Drug Development in Clinical Trials & GCP Inspections

Dr. Javroongrit (ASEAN) reported on the outcome of the two ICH GCG-endorsed APEC LSIF sponsored advanced workshops for regulators on Review of Drug Development in Clinical Trials and GCP Inspections that were both held in Bangkok, Thailand in 2009.

The *Review of Drug Development in Clinical Trials* advanced workshop was organised on February 2-6, 2009 in continuation of the preliminary workshop that was held on March 17-21, 2008. This event involved trainers from Health Canada, PMDA and PhRMA and welcomed 26 participants coming from APEC-LSIF regions (Chile, Indonesia, Malaysia, Peru, Philippines, Singapore, Thailand and Chinese Taipei), as well as the GCC and ASEAN (Brunei Darussalam).

The *GCP Inspections / Clinical Research* advanced workshop was held on March 2-6, 2009. The event was a continuation of the preliminary workshop that was held on May 27-30, 2008. The US FDA and Health Canada participated in this event where many of the trainees from the previous training event also participated. The advanced workshop included several lectures and six Clinical Trials mock site inspections.

Dr. Javroongrit concluded that these training modules provided essential knowledge on Clinical Review and GCP Inspections and reinforced regional and DRAs networks. She recommended that the training materials should be for reuse and for publication on the ICH GCG working area and where appropriate on the ICH Public website.

❖ *GCG-Endorsed Training*

ASEAN Training

Dr. Javroongrit (ASEAN) reported on the organisation of three GCG-endorsed regional training events for ASEAN to be held in Malaysia. The MedDRA training for which the MedDRA Management Board was nominated as ICH lead is scheduled for the last week of November 2009 and the agenda is currently under development. Concerning the organisation of the training on ICH Q5C and the ICH Q8-Q10 Guidelines, Dr. Javroongrit requested a contact point for the EU which was nominated as ICH lead party and proposed that these events be held in the third week of January 2010 and the last week of February 2010, respectively.

GCC Training

Prof. Bawazir (GCC) updated the GCG on the organisation of the training on ICH Q5A-Q5E Guidelines to be held in November 2009 and for which EU was nominated as the ICH lead. The

GCG noted that the program should be finalized by the end of June 2009 and that they will work with the ICH Secretariat to identify expert(s) from ICH parties to participate to the training event.

PANDRH Training

In Yokohama in 2007, the GCG had approved a regional Quality training event to be hosted by MERCOSUR in São Paulo.

Dr. Fitzgerald (PANDRH) informed the GCG that unfortunately MERCOSUR timelines did not match with GCG timeframes and a training event on Quality and Risk Management had already been organised by MERCOSUR in February 2008 in São Paulo, Brazil.

❖ ***APEC Harmonisation Centre***

Dr. Jang (DRA, South Korea) provided an overview on the establishment of the APEC Harmonisation Centre (AHC) located in Seoul, South Korea. The GCG noted that the objective of the AHC is to create international cooperative networks for harmonisation between regulators, industry experts, institutions, investors and policy makers to develop and disseminate harmonisation models across the Asia-Pacific region. Dr. Jang informed the GCG that the broad scope of activities of AHC will include the conduct of surveys and research to define harmonisation challenges and opportunities, to provide education programs, and to develop a website for posting AHC reports and publications. The GCG noted that the inauguration of the center in Seoul will be held on June 15, 2009 and will be followed by the organization on June 15-18, 2009 of the inaugural workshop of the AHC on Multi-Regional Clinical Trials for regulatory harmonization. As part of the AHC inauguration events, the LSIF Regulatory Harmonization Steering Committee (RHSC) will meet for the first time on June 17-18, 2009 in Seoul. Dr. Jang also informed the GCG of the preparation of two future AHC workshops to be held on September 16-18, 2009 and November 2009.

❖ ***Anticipating Future Training Needs***

The GCG noted that no new training requests had been submitted by the RHIs and DRAs. The GCG discussed the value of developing future training on CTD / eCTD, highlighting the benefit to use a common regulatory language among all regions.

❖ ***Other Training Events of Interest***

Mr. Ward (Health Canada) informed the GCG that the first Health Canada's *Health Products and Food Branch (HPFB) International Regulatory Forum* will be held in Ottawa, Canada on September 14-18, 2009. The Regulatory Forum is intended to provide an efficient and integrated opportunity for the exchange of information on health product regulation between Health Canada and counterpart regulators internationally. The final agenda will be available by the end of July 2009 on the Health Canada website. Also, Dr. Molzon (FDA) confirmed the date for the CBER forum which will take place on October 4-5, 2009.

❖ ***Evaluation of GCG training events***

Dr. Adam (ICH Secretariat) updated the GCG on the development of a training evaluation form to monitor and evaluate GCG-endorsed training events. The GCG made several suggestions on the content of the form. The Secretariat will collect the comments and once updated, the form will be circulated to the GCG for approval. The evaluation form is expected to be finalized by the time of the next ICH meeting in St. Louis, Missouri on October 24-29, 2009.

Actions/Decisions:

- *The ICH Secretariat will collect comments from the GCG on the training evaluation form and update it accordingly;*
- *Once finalized, the ICH Secretariat will circulate the revised form for GCG approval prior to the next ICH meeting.*

11. RHI and DRA update on ICH-related matters

RHIs and DRAs gave formal presentations to the GCG on their respective initiatives and current activities. The presentations will be posted on the ICH website.

APEC, Dr. Pavittranon provided background information on the APEC Life Sciences Innovation Forum (LSIF) and highlighted the effort of regulatory, industry and academia to promote greater synergies and coordination, to optimise benefits derived from interactions with international harmonization initiatives and to develop mechanisms to sustain training and capacity-building work. She reported on the sixth annual meeting (LSIF VI) that was held in Peru on August 14-15, 2008 and the preparation of the next LSIF meeting that will be held in Singapore on August 3-4, 2009.

ASEAN, Dr. Javroongrit reported on the outcome of the 16th PPWG meeting held in Manila, Philippines on May 28-29, 2009. Progress was made at the meeting on the ASEAN MRA (Mutual Recognition Agreement) for Pharmaceuticals including MRA-BA/BE (Bioavailability/Bioequivalence) studies and MRA-GMP Inspection. The GCG noted the adoption of a mechanism for the revision of ASEAN technical Guidelines. The GCG also noted the cooperation with international organisations and dialogue partners on Pharmaceuticals and on capacity building on vaccine regulatory framework. Dr. Javroongrit informed the GCG on other progresses made at the 16th PPWG (e.g., technical assistance and capacity building for the principal sector, establishment of the Joint Sectoral committee and extension of the PPWG Terms of References).

GCC, Prof. Bawazir reported on the organization, the mission and the current activities of the GCC-DR. He informed the GCG on the outcome of the 8th Middle East Regulatory Conference (MERC) held in Bahrain on January 20-21, 2009. The meeting focussed on pharmacovigilance, counterfeit medicines, innovation in the quality arena, CTD / electronic CTD, evolution of global legislation on medicines, and health economics. Prof. Bawazir reported to the GCG on the outcome of the Arab Union Pharmaceuticals and Medical Appliances (AUPAM) meeting in Amman, Jordan on May 30-31, 2009 where problems faced by manufacturers in registering pharmaceuticals were discussed. The two-day conference aimed at developing a draft on standardizing criteria affiliated with registering medicines in an attempt to establish a joint Arab pharmaceutical market. The GCG also noted the outcome of the CTD/eCTD workshop held in Dubai on May 30-31, 2009.

PANDRH, Dr. Fitzgerald provided background information on PANDRH including its structure and regional organisation. He informed the GCG on the outcome of the V PANDRH conference held in Buenos Aires on November 17-19, 2008 where over 250 participants from National Drug Regulatory Authorities (NRAs), Industry and Academia were welcomed. Important topics discussed at the meeting included pharmaceutical regulation and public health, update on drug regulatory harmonisation initiatives, system for inter-NRA recognition, essential functions in medicines regulation and challenges for NRAs, counterfeit as a public health problem, WHO pre-qualification, and adoption of harmonised technical documents in PANDRH's regions. The GCG

noted the organisation of the PANDRH Steering Committee meeting in July 2009 in PAHO offices, Washington D.C., USA.

SADC, Dr. Sitoie presented briefly the SADC history and provided background information on SADC's organisation and objectives. The GCG noted the progress made on Guideline development with the approval of seventeen Guidelines for the Registration and Control of Medicines in the SADC. She reviewed the current SADC projects on pharmacovigilance, counterfeit medicines and pooled procurement of medicines within the regions. Dr. Sitoie presented to the GCG SADC's two-year plan of action, which includes in addition to current projects, the ongoing implementation of Guidelines for the registration and the control of medicines, the assessment and capacity strengthening of National Regulatory Authorities. The GCG noted also the future planned activities within SADC to develop more regional trainings / capacity building events (on Quality and CTD) and centres of excellence. Dr. Sitoie reported also on the challenges faced by the Republic of Mozambique.

DRA of India, Dr. Singh provided background information on the Central Drugs Standard Control Organisation (CDSCO) structure and objectives. Dr. Singh highlighted the growing importance of Indian Pharma and biotech sectors since 2006 and provided some history on Indian regulations. The GCG noted that CDSCO developed new initiatives in collaboration with WHO and Health Canada (e.g., the introduction of CTD format, the development of Standard Operating Procedures, guidance and checklist documents; and the recruitment and training of staff) that led to the provisional NRA pre-qualification by WHO in April 2009. The GCG also noted the CDSCO future planned activities which includes the adoption of CTD format for all biological companies by 2010 and also by all drug manufacturers by 2015; the development of Pharmaceutical zones in Indian international ports for preserving the quality of medicines, and other enforcement measures such as mandatory Registration of Clinical Research Organizations and clinical trials, penal provision and strengthening pharmacovigilance.

12. Drivers and Success Factors for Harmonisation

Dr. Molzon (FDA) updated the GCG on the work of the small working group (EU, FDA, EFTA, Health Canada and DRA of Australia) regarding the development of a document describing drivers and success factors necessary for harmonisation. Dr. Molzon suggested to the GCG that the document would be a revision of the 'Values and Benefits' document dated November 2000 and could highlight the benefit of harmonisation in protecting, promoting and advancing public health. The GCG noted that the draft document would cover not only the benefits of ICH harmonisation but also some of the GCG activities. Dr. Molzon proposed that the document could be published in commemoration of the 20th anniversary of ICH, in 2010. The membership of the working group was extended with the participation of WHO, EFPIA and PANDRH. The group will work to prepare an action plan for SC approval.

Action/Decision:

- *The GCG supported the expansion of the small working group for the preparation of a formal action plan for SC approval describing the drivers and the success factors necessary for harmonisation.*

13. ICH update report

Dr. Ronan (ICH Secretariat) gave an update on the organisation of the Yokohama ICH meeting and the status of the Quality, Safety and Efficacy ICH topics:

S2(R1): The S2(R1) *Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use* EWG would be meeting in Yokohama to work towards reaching *Step 4*.

M3(R2): The M3(R2) *Revision of Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals* EWG would continue its work towards reaching *Step 4* in Yokohama.

S6(R1): In Yokohama, the S6(R1) *Revision of Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals* EWG would be working toward reaching *Step 2* of the *addendum* to the S6 Guideline which is currently expected in autumn 2009.

S9: In Yokohama, the S9 *Oncology Therapeutics* EWG would review comments from public consultation (*Step 3*) and continue its work towards reaching *Step 4*.

E2F: In Yokohama, the E2F EWG on *Development Safety Update Report* would meet to review comments from Public consultation (*Step 3*) and work towards reaching *Step 4*.

E7: The E7 IWG on *Studies in Support of Special Populations: Geriatrics* would be holding its first meeting in Yokohama and would work to progress its Q&As document to assist the implementation of E7.

E16: In Yokohama, the E16 *Genomic Biomarkers Related to Drug Response: Context, Structure and Format of Qualification Submissions* EWG would continue its work towards reaching *Step 2*.

Q4B: The Q4B *Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions* EWG was meeting in Yokohama and would continue its work to develop topic-specific annexes to the Q4B Guideline. The following annexes of Q4B were expected to reach *Step 2* in Yokohama: Annex 9 on *Tablet Friability* and Annex 10 on *Polyacrylamide Gel Electrophoresis*. The Q4B EWG would continue its work toward reaching *Step 4* of the annexes: Annex 5 on *Disintegration Test*, Annex 6 on *Uniformity of Dosage Units*, Annex 7 on *Dissolution Test* and Annex 8 on *Sterility Test*.

Q11: The Q11 *Development and Manufacture of Drug Substances* EWG would meet in Yokohama to continue its work towards *Step 2* which is currently expected in June 2010.

Quality IWG: The IWG focusing on the implementation of the Q8, Q9, Q10 ICH Guidelines completed the *Step 4* sign-off of the first set of Q&As in April 2009. The IWG would be working in Yokohama to develop a second set of 10 Q&As.

GTDG: The Gene Therapy Discussion Group would be working toward finalizing the ICH Considerations document on *Viral/Vector Shedding* at the Yokohama meeting.

14. Presentations on ICH Topics

The GCG, RHIs and DRAs received a presentation on the ICH topic M3(R2) on *Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals* which was expected to reach *Step 4* in Yokohama[♦].

Dr. Jacobs, FDA Rapporteur for M3(R2), summarized to the GCG the evolution of the Guideline and provided background on the revision of M3(R1) Guideline. The GCG noted that the revision ICH M3(R2) will include further harmonisation for non clinical safety studies to better define current recommendations and reduce the likelihood that substantial differences will exist between regions. The M3(R2) Guideline should facilitate the conduct of Clinical Trials, should have an impact on the 3R's and promote safe and ethical development and availability of pharmaceuticals.

15. Communication about GCG

GCG Public Website / Members Only

Dr. Adam (ICH Secretariat) updated the GCG on addition / improvements made in March 2009 to the ICH GCG Public website. The updates include, a library containing general presentations on ICH Guidelines, in addition to the general *Step 2/Step 4* presentations developed by EWGs and the training materials from GCG-endorsed training events; the RHI finalized profiles for ASEAN, GCC and PANDRH; and new GCG web pages to provide additional background information on the GCG and GCG activities. Dr. Adam presented mock-up web-pages of the updated GCG members website, which contains a calendar of training opportunities and harmonisation events with major regional events of interest to GCG, RHIs and DRAs and a GCG reference document section (e.g., agenda and reports, procedures, terms of reference, mission).

Action/Decision:

- *Once finalized, the ICH Secretariat will provide access to the GCG members, to the 'members only' GCG website.*

16. Any Other Business

ICH Public Meeting

Dr. Kishi (JPMA) updated the GCG on the organisation of the ICH Public meeting which would be held in Tokyo on Friday June 12, 2009. It was noted that more than six hundred participants from eighteen different countries registered to the event. The symposium would provide an update on the ICH Guidelines and also focus on the implementation of ICH Guidelines in Asian countries. Speakers would include Dr. Javroongrit (ASEAN), Dr. Kim (DRA, South Korea) and Dr. Lim (DRA, Singapore) in addition to a number of ICH experts from the three ICH regions and Health Canada.

[♦] The M3(R2) Guideline reached *Step 4* in Yokohama on June 11, 2009.