27 January 2016

MEETING REPORT
ICH Assembly
9 – 10 December 2015, Jacksonville, FL, USA

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

ICH Secretariat, Chemin des Mines 9, P.O. Box 195, 1211 Geneva 20, Switzerland

Telephone: +41 (22) 338 32 06 - admin@ich.org, http://www.ich.org

List of Assembly Participants

ICH Assembly Members & Observers:

Dr. Theresa Mullin	FDA	USA
Ms. Joan Wilmarth Blair	FDA	USA
Dr. Peter K. Honig	PhRMA	USA
Dr. Rajesh Ranganathan	PhRMA	USA
Ms. Lenita Lindström-Gommers	EC	Europe
Dr. Sébastien Goux	EC	Europe
Dr. Tomas Salmonson	EC/EMA	Europe
Mr. Richard Bergström	EFPIA	Europe
Dr. Sabine Luik	EFPIA	Europe
Dr. Toshiyoshi Tominaga	MHLW/PMDA	Japan
Dr. Nobumasa Nakashima	MHLW	Japan
Mr. Naoyuki Yasuda	MHLW/PMDA	Japan
Dr. Hironobu Saito	JPMA	Japan
Mr. Akira Kawahara	JPMA	Japan
Dr. Petra Doerr	Swissmedic	Switzerland
Ms. Cordula Landgraf	Swissmedic	Switzerland
Ms. Cathy Parker	Health Canada	Canada
Dr. Lembit Rägo	WHO	Switzerland
Mr. Michael Ward	WHO	Switzerland

ICH Coordinators:

Mr. Fumihito Takanashi	MHLW	Japan
Mr. Mitsuo Mihara	JPMA	Japan
Dr. Michelle Limoli	FDA	USA
Ms. Camille Jackson	PhRMA	USA
Mr. Pär Tellner	EFPIA	Europe
Dr. Sébastien Goux	EC	Europe
Dr. Celia Lourenco	Health Canada	Canada

Technical Coordinators:

Mr. Milton Boneli	EC/EMA	Europe

Others[1]:

Ms. Amanda Roache	FDA	USA
Ms. Emer Cooke	EC/EMA	Europe
Mr. Martin Harvey	EC/EMA	Europe
Mr. Yoshihiro Katsura		Japan
Dr. Hee Sung Kim		APEC
Ms. Jane Mashingia		EAC
Mr. Burhani Othman Simai		EAC
Prof. Ibrahim A. Aljuffali		GCC
Mrs. Ana Paula Jucá Silva		PANDRH
Ms. Fortunate Fakudze		SADC
Dr. John Donohoe		Australia
Dr. Renato Porto		Brazil
Ms. Patrícia Pereira		Brazil
Mr. Yuan Lin		China
Ms. Zhang Ying		China
Mr. Xinyu Weng		China
Mr. Huang Qingzhu		China
Dr. Li-Ling Liu		Chinese Taipei
Dr. Churn-Shiouh Gau		Chinese Taipei
Dr. Sun Hee Lee		Republic of Korea
Dr. Sergey Glagolev		Russia
Ms. Marieke van Dalen		API Industry
Dr. Lila Feisee		Biotech Industry
Dr. Susanne Keitel		EU Pharmacopeia
Dr. Nicholas Cappuccino		IGPA
Ms. Janeen Skutnik Wilkinson		IPEC
Dr. John S. Punzi		WSMI

ICH Secretariat:

Dr. Dawn Ronan	Switzerland
Dr. Sarah Adam	Switzerland

[1] At the Assembly meeting in Jacksonville, the Assembly welcomed SADC, GCC, PANDRH, APEC and the DRA of Brazil as the first ICH Observers of the Association.

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Opening Discussions

The ICH Assembly meeting in Jacksonville, FL, USA on 9 – 10 December 2015 was chaired by Mrs. Lindström-Gommers (EC, Chair), Dr. Tominaga (MHLW/PMDA, Vice-Chair) and Dr. Mullin (FDA, Associate Vice-Chair).

Adoption of the Agenda

The agenda was adopted without modification.

1. Presentation of the ICH Organisational Changes

The Associate Vice-Chair of the Assembly reported to the Assembly on ICH organisational changes and presented the new ICH Association (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) to the participants.

The Associate Vice-Chair presented the focus of the ICH Reforms highlighting the new governance structure, the improved transparency and openness of processes, the benefit of international outreach, the establishment of a new legal entity and of an alternative funding model for the new Association. The ICH Articles of Association which were adopted by ICH Founding Regulatory and Founding Industry Members at the Inaugural Assembly of the new ICH Association on October 23, 2015 were also presented, including the eligibility criteria, the rights and duties of Regulatory Members, Industry Members and Observers.

The report also presented the roles and responsibilities of the Assembly and the Management Committee (MC), the completion of the Membership/Observership Application process, the finalisation of the Rules of Procedure (RoPs) for the Assembly, and the progress made towards the finalisation of the MC RoPs in addition to the Standard Operating Procedures (SOPs) for Working Groups.

The RHIs and DRAs/DoH, who were former participants of the Global Cooperation Group (GCG) reported on the outcome of their respective discussions during their pre-meetings where they shared views on the ICH Reforms and the ICH Articles of Association. All participants shared views on the new ICH structure and function. The Southern African Development Community (SADC), the Gulf Cooperation Council (GCC), the Agência Nacional de Vigilância Sanitária (ANVISA) of Brazil, the Pan American Network for Drug Regulatory Harmonization (PANDRH), and the Asia-Pacific Economic Cooperation (APEC) were welcomed as the first Observers of the ICH Association.

The Chair of the Assembly encouraged other RHIs and DRAs/DoH to take the opportunity to automatically become ICH Observers before 23 January 2016, a privilege provided to the former GCG participants by the Articles of Association.

Assembly Decisions/Actions:

- *The Assembly welcomed SADC, GCC, PANDRH, APEC and the DRA of Brazil as the first ICH Observers of the Association;*
- *The Assembly tasked the Communication Sub-committee to develop a Questions and Answers document which would compile all questions received during the discussion on ICH Organisational Changes;*
- *Once finalised, the Q&A document will be made available on the ICH website.*

2. Update on the Assembly Rules of Procedure

The lead of the Rules of Procedure (RoP) Sub-committee of the MC reported to the ICH Assembly on the final RoPs for the Assembly.

Assembly Decisions/Actions:

- *The Assembly adopted the RoPs for the Assembly;*
- *The Assembly supported the RoPs be made available on the ICH website.*

3. Report on Membership and Observership Application Process

The lead of the Membership Sub-committee of the MC presented to the Assembly on the Membership and Observership application process and the application forms for becoming a Regulatory Member, an Industry Member or an ICH Observer to the ICH Association.

Templates for Membership and Observership applications were shared with the participants of the Assembly meeting. The Assembly noted that the Membership and Observership application forms will be made available on the ICH website following the Jacksonville meeting. As per the Articles of the Association, all applicants will be able to submit by email their completed application forms and the necessary documentation. The MC will be responsible for reviewing all new applications before the Assembly decides on the membership admissions at its subsequent face to face meeting. Decisions on membership admission will become effective on the date of decision taken by the Assembly.

Assembly Decisions/Actions:

- *The Assembly noted the process for Membership and Observership application;*
- *The Assembly supported the Membership and Observership Application forms be made available on the ICH website.*

4. Report on ICH Funding

The lead of the Financial Sub-committee of the MC presented to the Assembly on the funding of ICH during an initial transition period and shared future considerations.

The Assembly noted that the funding of ICH operations (Secretariat, meetings etc.) will initially be ensured by the Permanent Members of the MC. This will ensure continuation of ICH operations and will contribute to a smooth transition allowing time to prepare for introducing membership fees.

Following the transition period, the Assembly noted that the ICH Association shall be funded by membership fees which will be payable by all Members.

It was noted that ICH Members and Observers will commit to self-financed attendance in future ICH meetings and that the membership fees once finalised would need to be approved by the Assembly, on the basis of a proposal from the MC.

Assembly Decision/Action:

- *The Assembly approved as final the proposed 2016 ICH Budget.*

5. Annual Work Plan and Multi-Annual Strategic Plan of the Association

The Vice-Chair of the Assembly presented to the Assembly the draft 5-Year Strategic Plan of the Association including a list of proposed new ICH topics for future consideration by the Assembly. The Assembly noted the establishment of a Sub-committee of the MC to prepare a framework for collecting and prioritising new ICH topics received.

Assembly Decisions/Actions:

- *The Assembly noted the draft ICH 5-Year Strategic Plan for current ICH topics, and a list of new proposed ICH topics for harmonisation which were recently suggested;*
- *The Assembly supported the preparation of a framework for prioritisation of new topics will be prepared by a Sub-committee of the MC ahead of its teleconference to be held in Spring 2016;*
- *In its next meeting, the Assembly will be invited to provide its views and consider approval of the ICH 5-Year Strategic Plan including new topics for ICH Guidelines recommended by the MC, as well as approval of the Annual Work Plan for 2016.*

6. Implementation of ICH Guidelines

All regulatory participants were invited to update the Assembly on the status of implementation of ICH Guidelines in their respective countries and regions.

The Assembly Members and Observers took note of the written information included in the agenda and shared further information on the status of implementation of ICH Guidelines in their respective countries and regions.

7. ICH Training Activities

The Assembly received a status report on the establishment of an E-learning Center by the APEC Harmonisation Center (AHC); which included the development an ICH E-learning pilot programme for regulators and industry on the ICH E2 Series of Pharmacovigilance Guidelines. The E-Learning Center is expected to launch the pilot programme in February 2016 which would be open free of charge for a limited time period (6 to 12 months).

Assembly Decision/Action:

- *The Assembly congratulated the AHC on progress made in the development of the pilot programme on ICH E2 Guidelines in collaboration with ICH.*

8. Update on MedDRA

The Assembly received a report on the ICH MedDRA Management Board meeting held on 5 – 6 December 2015.

The Assembly noted that ahead of the meeting in Jacksonville, the Board had approved the 2016 Subscription Rates with no increase over the 2015 Rates. It was noted that the ability to keep rates flat for another consecutive year was as a result of continued growth of MedDRA subscribers throughout the world – currently numbering over 4,500 organisations – and increased efficiencies to contain costs for the maintenance and development of MedDRA.

The Assembly noted the importance of training in helping to facilitate the use of MedDRA and that the MSSO provides free training to Regulators and other MedDRA users as part of their MedDRA subscription package, with training available in several forms: face to face training; webinars; and e-learning tools/videocasts. The Assembly heard that in 2015 the MSSO had scheduled a total of 82 training courses which included 58 face-to-face training classes and 24 webinars. It was noted that a similar scale of training is planned for 2016, with all training offerings advertised on the website www.MedDRA.org.

The Assembly was updated on preparations for the implementation of the new 27th SOC (System Organ Class) with MedDRA 19.0 in March 2016. The new SOC, named *Product issues* will include terms relevant for issues with product quality, devices, manufacturing

quality systems, product supply and distribution, and counterfeit products. The Assembly noted that one of the goals of incorporating product quality terms into MedDRA is to support the recording of product quality issues and any associated adverse events by using a single terminology.

The Assembly was also informed of the release of a new version of the MedDRA Desktop Browser (MDB) in October 2015 which updates the user interface and the functions to match the Web-Based Browser (WBB) which was released in December 2014. Additionally, the MDB includes an option to change the user interface to any of the currently supported MedDRA languages, as well as supporting multiple languages and the display of hierarchy information in search result outputs.

The Assembly was also updated on ICH's work with the Council for the International Organizations of Medical Sciences (CIOMS) to develop Standardised MedDRA Queries (SMQs). In Jacksonville the Board acknowledged the significant contributions of the CIOMS SMQ Working Group (WG) and the development to-date of 98 SMQs. The Board also renewed the Memorandum of Understanding between ICH and CIOMS for a further year of development of new SMQs. In addition, the Board also congratulated CIOMS for its work on the second edition of the CIOMS SMQ WG's publication on *Development and Rational Use of Standardised MedDRA Queries,* which is due for publication in 2016.

Assembly Decision/Action:

- *The Assembly noted the decisions taken by the MedDRA Management Board.*

9. Status Report on Topics

At the start of the meeting in Jacksonville, the Assembly noted the current status of draft ICH Guidelines and predictions for progress towards *Step 2a/b* and *Step 4*. Updated information was provided during the Assembly meeting by the ICH Rapporteurs of the EWGs/IWGs meeting in Jacksonville.

10. S1 EWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline

The Rapporteur reported to the Assembly on the outcome of the S1 EWG meeting held on December 7 – 10, 2015.

The Assembly noted the current activities of the S1 EWG including the progress made towards the collection and review of confidential submissions of Carcinogenicity Assessment Documents (CADs) by sponsors to DRAs (from Europe, US, Japan, Canada and Switzerland) and the timeframe for the drafting of a *Step 1* Technical Document. A total of 25 CADs were received and analysed by the DRAs over the past 27 months. The Assembly noted that the S1 EWG was expecting to receive 2 new CADs per month which would delay for about 2 years the revision of the S1 Guideline. The Assembly also noted that December 2017 was the final deadline for the submission of all new CADs.

In such case, the ICH S1 Guideline will be expected to reach *Step 2a/b* by November 2019.

The Assembly noted that the S1 EWG will continue the collection of CADs and study report evaluations. The Rapporteur also informed the Assembly that the Regulatory Notice Document (RND) currently posted on the ICH website will be updated in January 2016 to reflect a change in regulatory membership (participation of Health Canada and Swissmedic in the CAD review group). The S1 EWG will also complete a Prospective Evaluation Period Status Report which will also be made available on the ICH website.

Assembly Decisions/Actions:

- *The ICH Assembly endorsed the publication in January 2016 on the ICH website of a modified RND to reflect the agreed upon procedural changes and the update of membership;*
- *The Assembly endorsed the publication on the ICH website of the S1 Status Report;*
- *The Assembly endorsed the work plan of the S1 EWG and its timelines for activities to be undertaken.*

11. S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Medicinal Products and Toxicity to Male Fertility

The Rapporteur reported to the Assembly on the outcome of the S5(R3) EWG meeting held on December 7 – 10, 2015.

The Assembly noted the group's progress related to the revision of the majority of the sections and notes of the ICH S5(R2) Guideline to address several identified issues such as: scope of the S5 Guideline, test system selection, dose selections parameters, integrated testing strategies for embryofoetal development testing, and performance standards. The Assembly also noted the complexity, novelty and number of topics to be addressed.

The Assembly noted that the ICH S5(R3) draft Technical Document was expected to reach *Step 1* and Step *2a/b* in June 2017.

Assembly Action/Decision:

- *The Assembly endorsed the work plan of the S5(R3) EWG for activities to be undertaken.*

12. S9 IWG: Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals

The Rapporteur reported to the Assembly on the outcome of the meeting of the S9 IWG meeting held on December 7 – 10, 2015.

The Assembly noted the current activities of the S9 IWG including the progress made towards developing the ICH S9 Q&As. It was noted that answers to questions were drafted for a majority of topics. The Rapporteur informed the Assembly that the group will continue its discussion with the ICH S11 EWG regarding the need for juvenile animal studies to clarify viewpoints of both groups. With regards to the application of the 3R's principle (Replacement, Reduction and Refinement), the Rapporteur explained that the clarification of the scope could decrease the conduct of toxicology studies. Discussions with the S5(R3) EWG were also suggested.

The Assembly noted that the ICH S9 Q&A document was expected to reach *Step 1* and *Step 2a/b* in Q1 2016.

Assembly Decisions/Actions:

- *The Assembly noted the new proposed timelines for the S9 Q&A document to reach Step 1 in Q1 2016;*
- *The Assembly requested that once Step 1 is reached, the Secretariat organises a postal sign-off (under Step 1) at the expert level which would be followed by Step 2a electronic endorsement by the Assembly and Step 2b electronic endorsement by the Regulatory Members of the Assembly;*
- *The Assembly recommended that the S9 IWG continues its discussions with the S11 EWG and engage also in discussions with the S5(R3) EWG;*

- *The Assembly endorsed the work plan of the S9 EWG for activities to be undertaken.*

13. S11 EWG: ICH Guideline on Nonclinical Safety Testing in Support of Development of Paediatric Medicines

The Rapporteur reported to the Assembly on the outcome of the meeting of the S11 EWG held on December 7 – 10, 2015 and progress made towards developing the ICH Guideline on *Nonclinical Safety Testing in support of Development of Paediatric Medicines*.

The Assembly noted the group collected data on juvenile animal studies conducted to support paediatric programmes in the last 5-10 years. It was noted that these data will add to the collective experience in conducting studies and point to areas where specific guidance is needed.

The Assembly noted that the ICH S11 draft Technical Document was expected to reach *Step 1* and *Step 2a/b* in June 2017.

Assembly Action/Decision:

- *The Assembly endorsed the work plan and proposed timelines of the S11 EWG for activities to be undertaken.*

14. Q12 EWG: ICH Guideline on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

The Rapporteur reported to the Assembly on the outcome of the Q12 EWG meeting held on December 6 – 10, 2015 and progress made towards developing the ICH Guideline on *Lifecyle Management*.

The Assembly noted the EWG progress made in Jacksonville regarding the characterisation of an effective Pharmaceutical Quality System (PQS), the establishment of conditions for new chemical and biotech/biological products, and the application of Q12 for currently marketed products and lifecyle management plan.

The Assembly noted that the ICH Q12 Technical Document was expected to reach *Step 1* and *Step 2a/b* in June 2017.

Assembly Decisions/Actions:

- *The Assembly noted the possible delay (up to 1 year) before the Q12 EWG reaches Step 1 and Step 2a/b in June 2017;*
- *The Assembly requested that the Q12 EWG provides a revised work plan for activities to be undertaken and timelines to the MC ahead of its teleconference to be held in spring 2016.*

15. E9(R1) EWG: Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses

The Rapporteur reported to the Assembly on the outcome of the E9(R1) EWG meeting held on December 7 – 10, 2015 and progress made towards developing the E9 Addendum on *Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses*.

The Assembly noted the importance of defining 'estimand' and improving the framework for clinical trial planning, conduct, analysis and interpretation, and the role of sensitivity analyses in this pathway. It was noted that generally, an estimand reflects what is to be estimated to address the scientific question of interest posed by a clinical trial. The choice of an estimand involves the following three attributes: population, endpoint, and measure of intervention effect.

The Assembly also noted that the E9(R1) EWG started the drafting of the Technical Document and proposed text to update ICH E9 and is discussing the need for and the content of a technical appendix to the E9 Addendum which will include the development of technical definitions and simple case studies to help facilitate discussion within the EWG.

The Assembly noted that the Addendum to ICH E9 was expected to reach *Step 1* and *Step 2a/b* in late 2016.

Assembly Decision/Action:

- *The Assembly endorsed the work plan of the E9(R1) EWG for activities to be undertaken.*

16. E14 IWG / Discussion Group (DG): The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drug

The Rapporteur reported to the Assembly on the outcome of the E14 IWG/Discussion Group (IWG/DG) meeting held on December 7 – 10, 2015 and progress made towards the finalisation (Step 4) of the revised Q&A #5.1 on Concentration-Response Relationship.

The Assembly noted the finalisation of the revised E14 Q&A and the proposed next steps for the group including the group's recommendation to include new experts in non-clinical drug development (ICH S7B) to discuss advances in the science and methods related to the clinical assessment of QT prolongation and to continue the discussion of the Comprehensive In Vitro Pro-arrhythmia Assessment (CIPA) initiative.

Assembly Decisions/Actions:

- *The Regulatory Members of the Assembly adopted the E14 Q&A under Step 4 after the E14 Experts signed-off Step 3 of the revised E14 Q&A on Concentration Response Relationships (CRR);*
- *The Assembly agreed to revert back to E14/S7B Discussion Group (DG) status with experts in clinical (E14) and non-clinical drug development (S7B);*
- *The Assembly endorsed the recommendation of the E14 IWG/DG not to reopen the E14 Guideline for a full revision;*
- *The Assembly requested the ICH Secretariat to update the membership of the E14/S7B DG;*
- *The Assembly requested the E14/S7B DG to provide a work plan for activities to be undertaken to the MC ahead of its teleconference to be held in spring 2016.*

17. E17 EWG: ICH Guideline on Multi-Regional Clinical Trials

The Rapporteur reported to the Assembly on the outcome of the E17 EWG meeting held on December 7 – 10, 2015 and progress made towards finalising the *Step 1* document on *Multi-Regional Clinical Trials (MRCTs)*.

The Assembly noted that this new ICH Guideline will provide general principles for the planning and design of MRCTs with the aim of encouraging the use of MRCTs in global regulatory submissions.

It was noted that MRCTs are generally the preferred option for investigating a new drug, which is planned to be approved for use in multiple regions and countries. However, to increase an acceptability of MRCT data in the review by multiple regulatory agencies for drug approval, a sponsor should carefully consider the planning and design of MRCTs in advance.

During the week, the group discussed several concepts to be included in the Guideline, such as sample size allocation and exploratory/confirmatory stage.

The impacts of the E17 Guideline were also presented. It will reduce the need to conduct standalone regional or national studies including bridging studies, promote international harmonisation and provide better evidences for drug approval in each region.

The Assembly noted that ICH E17 was expected to reach *Step 1* and *Step 2a/b* in Q1 2016.

Assembly Decisions/Actions:

- *The Assembly endorsed the revised work plan of the E17 EWG for activities to be undertaken;*
- *The Assembly requested that, once Step 1 is reached, the Secretariat organises a written postal sign-off (under Step 1) at the expert level which would be followed by Step 2a electronic endorsement by the Assembly and Step 2b electronic endorsement by the Regulatory Members of the Assembly.*

18. E18 EWG: ICH Guideline on Genomic Sampling and Management of Genomic Data

The Rapporteur reported to the Assembly on the outcome of the E18 EWG meeting held on December 6 – 9, 2015 and progress made towards finalising the *Step 1* Technical Document on *Genomic Sampling Methodologies for Future Use*.

The Assembly noted that the new E18 Guideline intends to provide considerations regarding patient privacy, data protection, informed consent and transparency and communication of findings. It was noted that the scope of this guideline pertains to genomic sampling and management of genomic data generated from clinical studies. In order to fit with the scope and contents of the E18 Technical Document the E18 EWG suggested changing the title of the Guideline to '*Genomic Sampling and Management of Genomic Data'*.

The Assembly noted that the group reached agreement in Jacksonville on the content of the Technical Document (*Step 1*) and that the consultation period (*Step 3*) will be launched very shortly.

The Assembly also noted that the ICH E17 was expected to reach *Step 4* in June 2017.

Assembly Decisions/Actions:

- *The Assembly endorsed Step 2a of the E18 Technical Document after the E18 Experts signed-off Step 1 of the E18 Technical Document;*
- *The Regulatory Members of the Assembly endorsed Step 2b of the E18 Technical Document;*
- *The Assembly endorsed the following new title for the E18 Guideline: 'Genomic Sampling and Management of Genomic Data';*
- *The Assembly requested the ICH Secretariat to revise the title of the E18 Concept Paper accordingly;*
- *The Assembly recommended that the Regulatory Members of the E18 EWG evaluate the possibility of reducing the E18 consultation period (Step 3) from the period proposed initially;*
- *The Assembly endorsed the work plan of the E18 EWG for activities to be undertaken.*

19. M2 EWG: Electronic Standards for the Transfer of Regulatory Information

The Rapporteur reported to the Assembly on the outcome of the M2 EWG meeting held on December 7 – 10, 2015.

The report included an update on coordination of ICH projects with Information Technology Requirements including: M2 Maintenance and information documents updates; coordination of ICH use of controlled vocabularies; revision of the information paper on redaction document; and addressing character length question for E2B.

The Rapporteur also presented to the Assembly an update on assessment and recommendation of technology and information standards including: ESTRI activities; SDO Monitoring and Technology Watch reviews; structured content research project; and electronic redaction of document requirements. The Rapporteur also highlighted the need to review the M2 operating model.

The Assembly noted that during the week, the group has finalised its Glossary of Terms and Abbreviation document.

The Assembly also noted the proposed work plan for major activities to be undertaken.

Assembly Decisions/Actions:

- *The Assembly endorsed the Glossary of Terms and Abbreviation document after the M2 Experts signed their agreement with the document;*
- *The Assembly requested that the Glossary of Terms and Abbreviation document be published on the ESTRI website;*
- *The Assembly requested that the M2 Experts develop a proposal for their new Operating Model (with input from MC Members) for MC discussion at its teleconference in Spring 2016;*
- *The Assembly endorsed the work plan including the development of the new M2 Operating Model.*

20. M8 EWG/IWG: The Electronic Common Technical Document: eCTD

The Rapporteur reported to the Assembly on the outcome of the M8 EWG/IWG meeting held on December 7 – 10, 2015.

The report will include an update on progress made regarding the finalisation of the eCTD version 4.0Implementation package v1.0 in addition to the finalisation of the Specification for Submission Formats for eCTD v1.0.

The Assembly noted the progress made by the group in updating the M4 Granularity Document (M4 Annex) based on Q&As from the M4Q(R1) IWG and change requests and its proposed timelines for *Step 4* sign-off of the M4 Annex.

The Assembly also noted the proposed work plan for major activities to be undertaken between Jacksonville and the next meeting in Europe in June 2016.

Assembly Decisions/Actions:

- *The Regulatory Members of the Assembly adopted under Step 4 the eCTD v4.0 Implementation Package v1.0 after the M8 Experts had signed-off Step 3 of the document;*
- *The Regulatory Members of Assembly adopted under Step 4 the Specification for Submission Formats for eCTD v1.0 after the M8 Experts also signed-off Step 3 of the document;*
- *The Assembly requested that the adopted Step 4 documents be published on the ESTRI website;*
- *The Assembly endorsed the plan and timelines after Jacksonville for Step 3 / Step 4 of the M4 Annex (Granularity document);*

- *The Assembly requested that once Step 3 is reached, the Secretariat organises a written postal sign-off (under Step 3) at the expert level;*
- *The Regulatory Members of Assembly noted that they would be invited to adopt as final under Step 4, the Granularity Document at the next Assembly meeting in Europe in June 2016;*
- *The Assembly endorsed the revised version of the M8 Concept Paper for publication on the ICH website;*
- *The Assembly endorsed the work plan of the M8 EWG/IWG for work to be undertaken.*

21. EWGs/IWGs/Discussion Groups not Meeting in Jacksonville, FL, USA

❖ ***S3A IWG: Q&As on Note for Guidance on Toxicokinetics***

The S3A IWG did not meet in Jacksonville.

The Assembly noted the current activities of the S3A IWG including the progress made towards developing the ICH S3A Q&As.

The Assembly noted that the ICH S3A Q&As document was expected to reach *Step 1* and *Step 2a/b* in February 2016.

Assembly Decisions/Actions:

- *The Assembly requested that once Step 1 is reached, the Secretariat organises a written postal sign-off (under Step 1) at the expert level which will be followed by Step 2a electronic endorsement by the Assembly and Step 2b electronic endorsement by the Regulatory Members of the Assembly;*
- *The Assembly requested that the S3A IWG provides a work plan to the MC ahead of its teleconference to be held in spring 2016 for activities to be undertaken.*

❖ ***M7(R1) EWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk***

The M7(R1) EWG did not meet in Jacksonville.

The Assembly noted the current activities of the M7(R1) EWG including the progress made towards collecting comments on the M7(R1) Addendum on *Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk*. The Assembly also noted that the comment period would end in January 2016.

The Assembly noted that depending on the number of comments received, the Addendum of the ICH M7(R1) Guideline was expected to reach *Step 3* and *Step 4* in Q2 2016.

Assembly Decisions/Actions:

- *The Assembly requested that once Step 3 is reached, the Secretariat organises a written postal sign-off (under Step 3) at the Regulatory expert level;*
- *The Assembly noted that the Regulatory Members of the Assembly would be invited to adopt as final under Step 4 the M7(R1) Guideline at the next Assembly meeting in Europe in June 2016;*
- *The Assembly requested that the M7(R1) EWG provides a work plan to the MC ahead of its spring teleconference to be held in Spring 2016 for activities to be undertaken.*

❖ ***Q3C(R6) Maintenance EWG: Maintenance of the Guideline for Residual Solvents***

The Q3C(R6) Maintenance EWG did not meet in Jacksonville.

The Assembly noted the current activities of the Q3C(R6) EWG and progress made collecting comments on the draft Part V of the Q3C(R5) Guideline. The Assembly also noted that the comment period would end in December 2015.

The Assembly noted that the ICH Q3C(R6) Guideline was expected to reach *Step 3* in March/April 2016.

Assembly Decisions/Actions:

- *The Assembly requested that once Step 3 is reached, the Secretariat organises a written postal sign-off (under Step 3) at the Regulatory expert level;*
- *The Assembly noted that the Regulatory Members of the Assembly would be invited to adopt as final under Step 4, the ICH Q3C(R6) Guideline at the next Assembly meeting in Europe in June 2016;*
- *The Assembly endorsed the work plan of the Q3C Maintenance EWG for activities to be undertaken.*

❖ ***Q3D IWG: Guideline for Metal Impurities***

The Q3D EWG/IWG did not meet in Jacksonville.

The Assembly noted the Q3D IWG completed modules 0 to 7 of its Q3D training package and was finalising modules 8 and 9.The Assembly noted that once finalised the 9 training modules (including audio-recordings) covering the key sections of the ICH Q3D Guideline will be posted on the ICH website. The Assembly also noted that regional workshops will be held in the different ICH regions in Q1 2016.

Assembly Decisions/Actions:

- *The Assembly endorsed the final training modules 0 to 7 after the Q3D Experts signed-off support of the documents;*
- *The Assembly noted the need to discuss and develop rules for the organisation of future regional ICH-endorsed events.*

❖ ***Q11 IWG: Q&As on API Starting Materials***

The Q11 IWG did not meet in Jacksonville.

The Assembly noted the current activities of the Q11 IWG including the progress made towards developing the ICH Q11 Q&As

The Assembly noted that *Step 3* / *Step 4* for the ICH Q11 IWG Q&As were expected by Q2/Q3 2016.

Assembly Action/Decision:

- *The Assembly requested that the Q11 IWG provides an updated work plan for activities to be undertaken to the MC ahead of its spring teleconference to be held in spring 2016.*

❖ ***M4Q(R1) IWG: Addressing CTD-Q-Related Questions/Change Requests Raised by the M8 EWG/IWG***

The M4Q(R1) IWG did not meet in Jacksonville.

The Assembly noted that the M4Q(R1) (CTD-Quality) IWG provided answers to all questions received by the M8 EWG/IWG; and also provided recommendations to M8 on revising the Granularity document (which is now an annex to ICH M4 Guideline).

The Assembly also noted that a remaining task for this IWG would be to develop a process for addressing future questions pertaining to CTD-Q.

Assembly Decision/Action:

➢ *The Assembly requested that the M4Q(R1) IWG provides a Status Report to the MC ahead of its teleconference to be held in spring 2016 .*

❖ ***E6(R2) EWG: Integrated Addendum to Good Clinical Practice (GCP)***

The E6(R2) EWG did not meet in Jacksonville.

The Assembly noted the current activities of the E6(R2) EWG and progress made towards collecting public comments on the draft Addendum on *Good Clinical Practice*. The Assembly also noted that the period comment would end in January 2016 and that a webinar for which seats are still available will be organised by the ICH Secretariat on December 15, 2015.

The Assembly also noted that *Step 3* and *Step 4* for the Addendum to ICH E6 were expected by June 2016.

Assembly Decision/Action:

➢ *The Assembly endorsed the work plan of the E6(R2) EWG for activities to be undertaken.*

❖ ***E11(R1) EWG: Addendum to Paediatric Drug Development***

The E11(R1) EWG did not meet in Jacksonville.

The Assembly noted the current activities of the E11(R1) EWG and progress made towards developing the E11 Addendum on *Paediatric Drug Development*.

The Assembly noted that *Step 1* and *Step 2a/b* for the Addendum to ICH E11(R1) were expected by June 2016.

Assembly Decision/Action:

➢ *The Assembly endorsed the work plan of the E11(R1) EWG for activities to be undertaken.*

❖ ***M4E(R2) EWG: Revision of CTD-Efficacy Guideline***

The M4E(R2) IWG did not meet in Jacksonville.

The Assembly noted the current activities of the M4E(R2) EWG and progress made towards collecting public comments on the revised *CTD-Efficacy* Guideline.

It was noted that the public comment period was being completed in the ICH regions and all comments received will be considered and discussed in monthly teleconferences beginning in January 2016.

The Assembly noted that *Step 3* and *Step 4* for ICH M4E(R2) were expected by June 2016.

Assembly Decision/Action:

- *The Assembly endorsed the work plan of the M4E(R2) EWG for activities to be undertaken .*

❖ ***E2B(R3) IWG: Revision of the Electronic Submission of Individual Case Safety Reports***

The E2B(R3) IWG did not meet in Jacksonville.

The Assembly was updated on the current activities of the E2B(R3) IWG and sub-group and activities. The Assembly noted that a Q&A document will be developed by the E2B(R3) IWG.

Assembly Decision/Action:

- *The Assembly requested that the E2B(R3) IWG provides an updated work plan for activities to be undertaken to the MC ahead of its teleconference to be held in spring 2016 .*

❖ ***M1 PtC WG: MedDRA Points to Consider (PtC) Working Group***

The M1 PtC WG did not meet in Jacksonville.

The Assembly noted the current activities of the M1 PtC WG with respect to the updating with each MedDRA release of the two PtC documents on *Term Selection* and *Data Retrieval and Presentation*.

Assembly Decisions/Action:

- *The Assembly endorsed the work plan of the M1 PtC WG for activities to be undertaken.*

22. Communication about ICH

Update on Communication Activities for 2016

The Lead of the Communication Sub-committee of the MC presented to the Assembly a proposed plan for ICH Communication activities in 2016 which will include the development of a communication strategy in addition to updating the ICH website to reflect the recent establishment of the new ICH Association.

ICH Regional Public Meetings

The Assembly noted that JPMA will be organising an ICH regional public meeting to be organised in Tokyo following the ICH meeting scheduled to be held in Osaka, Japan on November 5-10, 2016.

Dates of Next Meetings for 2016

June 11-16, 2016	Lisbon, Portugal (to be confirmed)
November 5-10, 2016	Osaka, Japan

EWG/IWGs Meeting in Europe

A list of EWG/IWGs which will meet face-to-face at the next ICH meeting in Europe on June 11-16, 2016 will be made available on the ICH public website following the Management Committee teleconference to be held in spring 2016.