

ICH ASSOCIATION

2017 ANNUAL REPORT



ICH Association
2017 Annual Report

*Prepared by the ICH Secretariat with the ICH Management Committee and MedDRA
Management Committee approval of their respective sections.*

Version dated 8 May 2018

Approved by the ICH Assembly on 6 June 2018

Message from Assembly Chair and Vice Chair

2017 was a year of continued growth for the ICH Association which saw the joining of new Regulatory Members CFDA, China and HSA, Singapore. ICH now has a total of 15 Members and 24 Observers, the integration of who is especially visible in the Assembly, where discussions have been enriched through the new perspectives offered. ICH's 23 Working Groups, which at the end of 2017, included over 500 technical experts, are equally enriched, with almost a third of experts now coming from organisations only having joined ICH since the establishment of the Association at the end of 2015.

While involving these new organisations in ICH Guideline development is of great importance, equally important for ICH is assisting guideline implementation by its Members in order to achieve truly global harmonisation. 2017 saw significant steps taken in support of this goal with activities such as the establishment of an Implementation Subcommittee and the launch of a training pilot with particular focus on ICH "Tier 1" and "Tier 2" Guidelines.

ICH hopes that these new activities will be beneficial to international harmonisation efforts as ICH and its Members work together to improve global public health and facilitate patient access to safe, effective and quality medicines. As Chair and Vice-Chair of the Assembly we are delighted to have the opportunity to see ICH through its continued evolution following our re-election by the Assembly in November 2017 for a second 2-year term.



Mrs. Lenita Lindström-Gommers
ICH Assembly Chair
EC, Europe



Dr. Toshiyoshi Tominaga
ICH Assembly Vice Chair
MHLW/PMDA, Japan

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1. About ICH

1.1. Purpose & Aims

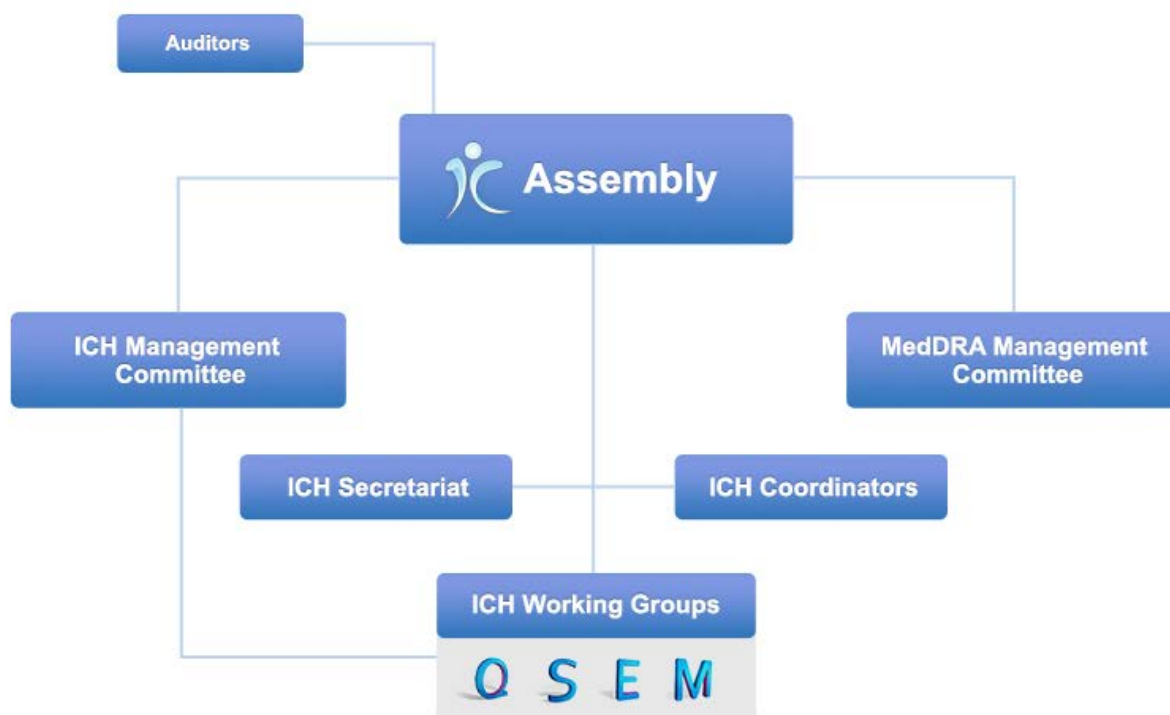
The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is an **international non-profit organisation** which was established as an association under Swiss law in October 2015. The purpose of ICH is to **promote public health through international harmonisation** of technical requirements that contributes to the timely introduction of new medicines and continued availability of the approved medicines to patients, to the prevention of unnecessary duplication of clinical trials in humans, to the development, registration and manufacturing of safe, effective, and high quality medicines in an efficient and cost-effective manner, and to the minimization of the use of animal testing without compromising safety and effectiveness.

The **ICH's aims** are the following:

- ✧ To make recommendations towards achieving **greater harmonisation** in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration and the maintenance of such registrations;
- ✧ To maintain a forum for a **constructive dialogue** on scientific issues between regulatory authorities and the pharmaceutical industry on the harmonisation of the technical requirements for pharmaceutical products;
- ✧ To contribute to the **protection of public health** in the interest of patients from an international perspective;
- ✧ To monitor and update harmonised technical requirements leading to a **greater mutual acceptance** of research and development data;
- ✧ To **avoid divergent future requirements** through harmonisation of selected topics needed as a result of therapeutic advances and the development of new technologies for the production of medicinal products;
- ✧ To facilitate the adoption of **new or improved technical research and development approaches** which update or replace current practices;
- ✧ To encourage the **implementation and integration of common standards** through the dissemination of, the communication of information about and provision of training on, harmonised guidelines and their use;
- ✧ And to develop **policy for** the ICH Medical Dictionary for Regulatory Activities Terminology (**MedDRA**) whilst ensuring the scientific and technical maintenance, development and dissemination of MedDRA as a standardised dictionary which facilitates the sharing of regulatory information internationally for medicinal products used by humans.

1.2. Organisational Structure

The bodies of the ICH Association are the: **Assembly**; **ICH Management Committee**; **MedDRA Management Committee**; **ICH Secretariat** and **Auditors**. Although not a body of the Association, ICH Coordinators play an important role in supporting the work of ICH.



Assembly

- ✧ The Assembly brings together all Members and Observers of the ICH Association. It is the **overarching governing body** of ICH and adopts decisions in particular on matters such as the ICH Articles of Association, admission of new Members and Observers and adoption of ICH Guidelines.
- ✧ The full list of Assembly Member Representatives and Observer Delegates as of December 31, 2017 is provided in Annex I.

ICH Management Committee

- ✧ The ICH Management Committee is the body that oversees **operational aspects** of ICH on behalf of all Members, including administrative and financial matters and oversight of the Working Groups (WGs). The ICH Management Committee is responsible for submitting recommendations or proposals to the Assembly in preparation of Assembly discussions.
- ✧ The full list of the ICH Management Committee Member Representatives and Observer Delegates as of December 31, 2017 is provided in Annex II.

MedDRA Management Committee¹

- ✧ The MedDRA Management Committee has responsibility for **direction of MedDRA**, the Medical Dictionary for Regulatory Activities, ICH's standardised medical terminology.
- ✧ The full list of MedDRA Management Committee Representatives and Observer Delegates as of December 31, 2017 is provided in Annex III.

ICH Secretariat

- ✧ The ICH Secretariat is responsible for **day-to-day management** of ICH, coordinating ICH activities as well as providing support to the Assembly, ICH Management Committee and its WGs. The ICH Secretariat also provides support for the MedDRA Management Committee as the "MedDRA Secretariat".
- ✧ The full list of ICH Secretariat Staff as of December 31, 2017 is provided in Annex IV.

Auditors

- ✧ In 2016, the Assembly agreed to appoint Moore Stephens Refidar SA for an initial period of 2 years to audit the **annual financial statements** of the ICH Association.

ICH Coordinators

- ✧ Fundamental to the smooth running of ICH has been the designation of an ICH Coordinator per ICH Member to act as the main contact point with the ICH Secretariat. Coordinators ensure proper distribution of ICH documents to the appropriate persons from their organisation and are responsible for the **follow up on actions** within their respective organisation within assigned deadlines. They also assist communication between the ICH Management Committee and/or Assembly and the ICH WGs as needed.
- ✧ The full list of ICH Coordinators as of December 31, 2017 is provided in Annex V.

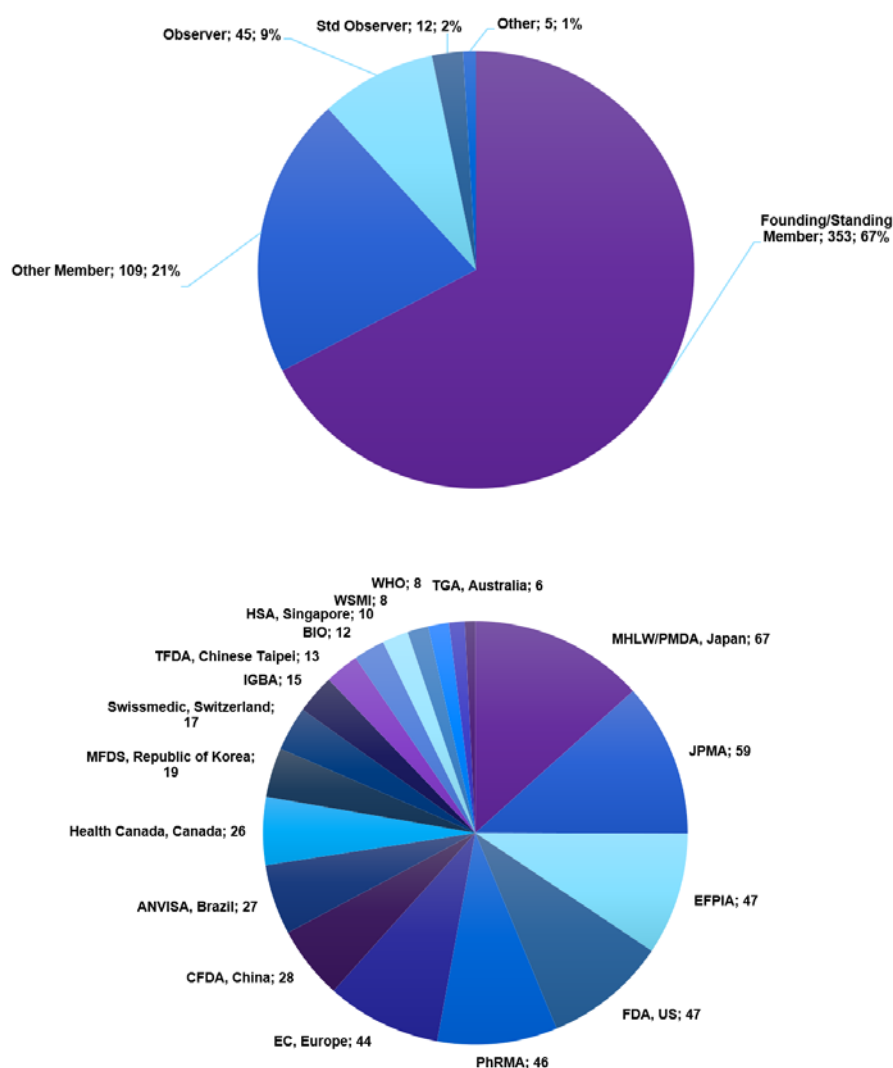
¹ In 2017, in view of the fact that MedDRA's ownership only transferred from trustee IFPMA to the new ICH Association in November, both the new MedDRA Management Committee and the former MedDRA Management Board operated in parallel until November, with the MedDRA Management Committee only being responsible prior to this for MedDRA decision-making pertaining to items relevant for the ICH Association.

2. 2017 Overview of ICH Membership & Observership

2.1. Continued Expansion of ICH Membership & Observership

A driving factor of the organisational change celebrated by ICH at the end of 2015 was to make ICH a **truly global initiative**. 2017 built upon 2016's success in expanding ICH's reach, with the addition of more new Members and Observers, bringing ICH to a total of **15 Members and 24 Observers**, thereby further expanding the forum for dialogue on scientific issues between regulatory authorities and the pharmaceutical industry on the harmonisation of the technical requirements for pharmaceuticals products.

These new Members and Observers have demonstrated great interest in participating in the activities of ICH, something which is particularly evident looking at ICH's **WGs**. At the end of 2017 these WGs involved the participation of **over 500 technical experts**, with almost a third of these experts coming from new ICH Members and Observers.



Overview of Expert Participation in ICH, as of 7 November 2017

While the expansion of ICH is celebrated by all involved, it also brings the challenge of ensuring the continued smooth operation of the Assembly and ICH WGs. In 2017, the ICH Management Committee carefully oversaw the appointment of experts to ICH WGs, weighing decisions on the addition of new experts against the size of WGs and the status of work, which sometimes meant not all requests to appoint experts could be accommodated. This is an area which the ICH Management Committee will continue to work on 2018.

2.2. New Members & Observers Approved in 2017

The Assembly approved **2 new ICH Regulatory Members** in 2017, based on the recommendation of the ICH Management Committee:

- ✧ CFDA, China
- ✧ HSA, Singapore



ICH Assembly Montreal, Canada, June meeting

Left to right: Mr. Xiangyu Wang (CFDA, China), Ms. Lenita Lindström-Gommers (EC, Europe), Dr. Toshiyoshi Tominaga (MHLW/PMDA, Japan), Dr. Theresa Mullin (FDA, US), Mr. Yuan Lin (CFDA, China), Dr. Wei Zhou (CFDA, China).



ICH Assembly Geneva, Switzerland, November meeting

Left to right: Dr. Theresa Mullin (FDA, US), Dr. Dorothy Toh (HSA, Singapore), Ms. Lenita Lindström-Gommers (EC, Europe), Dr. Toshiyoshi Tominaga (MHLW/PMDA, Japan).

3 New Observers were also approved by the Assembly in 2017 based on the recommendation of the ICH Management Committee:

- ✧ INVIMA, Colombia
- ✧ PIC/S
- ✧ The Bill & Melinda Gates Foundation

In addition to these approved Membership and Observership applications, in 2017 the Assembly also considered a number of other applications from organisations which did not meet the eligibility criteria. The ICH Management Committee also coordinated with the ICH Secretariat in 2017 to respond to further enquiries regarding interest in ICH Membership and Observership from organisations/individuals which in line with the procedures would not be eligible.

2.3. Participation of IFPMA National Association Experts

In 2017, the Assembly welcomed IFPMA's implementation of a process to enable **IFPMA national association experts** to participate in ICH WGs, making use of IFPMA's right as a Standing Observer to appoint one expert to each WG. This is an important step in connecting with industry stakeholders from the countries/regions of ICH's new Regulatory Members.

2.4. Communication of ICH Membership

Further to the ICH Management Committee's approval in 2016 of a **new ICH Member Logo**, the ICH Management Committee gave its support in 2017 to the translation of the word "Member". This will enable ICH Members to communicate their Membership in ICH in their own language within their own publications, presentations or on their websites after the signing of a disclaimer.

3. 2017 ICH Harmonisation Activities

A major output of ICH's work, in line with the specific aims of the organisation, is the development of **harmonised technical guidelines** on Quality, Safety Efficacy and Multidisciplinary topics.



In 2017, these activities were progressed on **24 topics** by technical WGs [including Expert Working Groups (EWG), Implementation Working Groups (IWG) and a Discussion Group (DG)], with support from the ICH Secretariat and under the oversight of the ICH Management Committee, with reporting to the Assembly. These activities were progressed via email and teleconferences, with some of the WGs being approved to

meet face-to-face by the ICH Management Committee to progress their activities at the time of ICH's biannual meetings in 2017. The ICH WGs which met in 2017 are presented in Annex VI.

The **key outcomes in 2017** relating to ICH harmonisation efforts include:

✧ Completion at **Step 4** of the ICH process and **finalisation** of work on:

- ✧ **2 New** ICH Guidelines
- ✧ **2 Revised** ICH Guidelines
- ✧ **2 New** Questions & Answers (Q&A) Documents
- ✧ **2 Updated** Q&A Documents
- ✧ **1 New** User Guide

✧ Reaching of **Step 2a/b** of the ICH process and completion of drafts of:

- ✧ **1 New** Guideline
- ✧ **2 Revised** ICH Guidelines

✧ **1 New** topic and **1 Revision** approved for development

An overview of all ICH WG activities and accomplishments in 2017 is presented in Annex VII.

3.1. ICH Guidelines & Other Documents Adopted at Step 4 in 2017

The following ICH Guidelines and other documents were adopted by the Regulatory Members of the Assembly at **Step 4** of the ICH process in 2017 following the reaching of consensus within the respective ICH WGs and sign-off by the Regulatory Member experts of these WGs under **Step 3**.

ICH E2B(R3) Guideline – Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (ICSR)

The ICH E2B(R3) Guideline aims to **standardise the essential clinical safety data** with recommendation on their specifications for electronic transmission.

In 2017, the following final documents were adopted:

- ✧ Additional **Q&As** v2.1 in the ICSR Implementation Guide package
- ✧ **Code Lists**: #9, #14 and #26
- ✧ EDQM Dose Form and Route of Administration Term **User Guide**

ICH E11 (R1) Guideline – Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population

The finalisation of the **Addendum** to the ICH E11 Guideline on clinical investigation of medicinal products in the pediatric population **addresses new scientific and technical knowledge advances in pediatric drug development** and updates certain aspects of the ICH E11 Guideline adopted in 2000. The ICH E11(R1) amendment includes guidance on ethical considerations, age classifications and subgroups for children, pediatric formulations and guidance on extrapolation in pediatric drug development and trial design.

ICH E17 Guideline – General Principles for planning and Design of Multi-Regional Clinical Trials

The finalisation of the **new** ICH E17 Guideline on the planning and design of multi-regional clinical trials (MRCTs) is intended to **facilitate the acceptability of MRCTs as part of global regulatory submissions** in ICH and non-ICH regions, as well as making it easier to seek approval of global trials. Facilitating the conduct and acceptability of MRCTs is expected to have a direct public health benefit, in particular by encouraging more predictability around the approval of trials and the use of clinical trial data from a greater variety of countries and regions.

ICH E18 Guideline – Genomic Sampling and Management of Genomic Data

The finalisation of the **new** E18 ICH Guideline on genomic sampling and management of genomic data clarifies that **genomic data should be collected in clinical trials and other studies in accordance with certain methodologies** during drug development and throughout the product life cycle; the guideline also covers the storage and retention of genomic samples.

ICH S3A Guideline – Q&As: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies

The final **Q&A** document on the ICH S3A Guideline aims to facilitate the implementation of the guideline and **promote the use of new micro-sampling techniques in toxicokinetic assessment** to contribute to the improvement of animal welfare, for example by reducing pain and distress in animals and the number of animals used in studies. The Q&A document also contributes to the more precise evaluation of the relationship between safety data and drug exposure in animals in drug development.

ICH Q11 Guideline – Q&As: Selection and Justification of starting Materials for the Manufacture of Drug Substances

This final **Q&A** document is intended to provide **additional clarification and promote convergence on the considerations** for the selection and justification of starting materials, and on the information that should be provided in marketing authorisation

applications and/or Master Files. The focus of the Q&A document is on chemical entity drug substances.

ICH M7(R1) Guideline – Addendum: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

The final M7(R1) **Addendum** to the guideline on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk provides a **list of compounds for which mutagenic potential and the threshold of toxicological concern have been established**.

ICH M8 – Electronic Common Technical Document (eCTD)

ICH M8 is a technical standard and Implementation Guide **to facilitate the exchange of regulatory information prepared in accordance with the requirements of the CTD** in the ICH regions. The M8 EWG/IWG in charge of this standard also assumes the responsibility for the implementation and maintenance of eCTD, as well as development and maintenance of other related documents such as Q&As and Study Tagging File specifications. All electronic standards documents are available on the Electronic Standards for Transfer of Regulatory Information (ESTRI) at <http://estri.ich.org>.

In 2017, several documents related to the M8 eCTD were adopted:

-  The eCTD **Study Tagging Files (STF) Stylesheet** v2.3
-  The eCTD v3.2.2 **Q&A** and Specification **Change Request** Documents v1.30
-  The eCTD v4.0 **Q&A** and **Change Request** Document v1.1

3.2. ICH Guidelines & Other Documents Endorsed at Step 2a/b in 2017

In 2017 the following ICH Guidelines and other documents were endorsed first at **Step 2a** of the ICH process by all Members of the Assembly, followed by endorsement at **Step 2b** by the Regulatory Members of the Assembly. This endorsement followed the reaching of consensus within the respective ICH WGs and sign-off by all Member experts of these WGs, under **Step 1**.

ICH E9 Guideline – Addendum: Statistical Principles for Clinical Trials

The **draft** ICH E9(R1) **Addendum** on defining appropriate estimands for a clinical trial/sensitivity analyses published for regulatory public consultation in 2017 **seeks to promote harmonised standards on the choice of estimand in clinical trials** and define an agreed framework for planning, conducting and interpreting sensitivity analyses of clinical trial data.

ICH Q12 Guideline – Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

The **new draft** ICH Q12 Guideline, which includes **2 Annexes**, on pharmaceutical product lifecycle management published for regulatory public consultation in 2017, **serves to provide guidance on a framework to facilitate the management of chemistry, manufacturing and control (CMC) changes to approved medicines**. In addition to providing more predictability for handling CMC changes, the Q12 Guideline is intended to contribute to public health by promoting innovation and the continual improvement of medicines.

ICH S5(R3) Guideline – Revision: Detection of Toxicity to Reproduction for Human Pharmaceuticals

The **draft revised** ICH S5(R3) Guideline on the detection of toxicity to reproduction for human pharmaceuticals published for regulatory public consultation in 2017 **seeks to enhance human risk assessment, while also potentially reducing animal use**. The revision uses experience gained since the last revision in 2000 with the testing of pharmaceuticals as well as developments in scientific, technological and regulatory knowledge.

3.3. Other Working Groups Outputs

The following highlights other noteworthy outputs of ICH WGs in 2017 outside of those items produced as part of the ICH step process.

- ✧ In March and September, the ICH M1 Point to Consider (PtC) WG updated the **two MedDRA PtC documents on Term Selection and Data Retrieval and Presentation** with MedDRA release versions 20.0 and 20.1.
- ✧ The M2 EWG on finalised a **new PDF specification** for publication on the ESTRi website at <http://estri.ich.org>.

3.4. New Harmonisation Activities

3.4.1. Strategic Reflection Papers

In 2017, the ICH Management Committee supported the following activities in relation to the Strategic Reflection Papers aimed at identifying potential areas of work:

- ✧ Further to Assembly support, in January 2017 ICH shared a Reflection Paper on the **Good Clinical Practice (GCP) Renovation** via the [ICH website](#) and invited public review and comments which were then taken into consideration by the ICH Management Committee in determining the approach. The goal of the GCP Renovation is to provide **updated guidance** that is both appropriate and flexible enough to **address the increasing diversity of study types and data sources** that are being employed to support regulatory and other health policy decisions, as appropriate. The underlying principles of human subject protection and data quality would remain. Included in the GCP Renovation approach is the **revision**

of the 1997 ICH E8 Guideline on General Considerations for Clinical Trials which is one of the new topic proposals approved by the Assembly in 2017 (see below)

- ✧ Further development by PhRMA of a **Quality Reflection Paper on Advancing Pharmaceutical Quality Standards**.
- ✧ Initiation of work by PhRMA to develop Reflection Papers on **Model Informed Drug Development (MIDD)** and **Patient Focused Drug Development (PFDD)** focused on technical issues e.g., related to the development and use of Patient Reported Outcomes.
- ✧ The initiation of work by EC, Europe on a **Vaccines Reflection Paper**, and FDA, US on a **Generic Drug Harmonisation Reflection Paper**.
- ✧ To put on hold work to further consider the development of a Reflection Paper on Compliance of Reliability for Electronic Records, which had been led by JPMA, with agreement to task the M2 EWG to watch this potential issue as part of its remit to review the external environment.

3.4.2. Approval of 2 New Efficacy Work Items

In 2017, using the process established in 2016 for the selection of new topics proposed for harmonisation by ICH Members and Observers, the ICH Management Committee and its New Topics Subcommittee assessed **16 new topic proposals** which had been submitted by a mid-January 2017 deadline. Further to this, a **short-list of 8 proposals** was prepared for the Assembly, and following prioritisation by the ICH Management Committee, **2 Efficacy topic proposals were recommended** having received the highest scores in the ICH Management Committee's prioritisation.

Based on the ICH Management Committee recommendation, the Assembly approved the following new harmonisation activities:

ICH E8(R1) Guideline – Revision of General Considerations for Clinical Trials

The **revision** of the ICH E8 Guideline on general considerations for clinical trials which is part of ICH's **GCP Renovation** plan will look at study design, planning and conduct, with a focus on identifying and supporting a basic set of critical-to-quality factors. In complement of its work on the ICH E8(R1) Guideline, the E8(R1) EWG will also be involved in the development of a **GCP Stakeholder Engagement Plan** in collaboration with the Communication Subcommittee of the ICH Management Committee, with agreement already reached to hold a **meeting with stakeholders** at the end of *Step 2b*, likely in June 2019.

- ✧ The Assembly adopted the E8(R1) Concept Paper outline at its meeting in Montreal in June 2017, following which an informal WG worked to finalise the Concept Paper and Business Plan which were then endorsed by the ICH Management Committee at its meeting in Geneva in November 2017.
- ✧ The Assembly appointed FDA, US as Rapporteur.

ICH E11A Guideline – Paediatric Extrapolation

Development of the **new** ICH E11A Guideline aims to **further advance the use of paediatric extrapolation** providing guidance on incorporating extrapolation methods in an overall approach to paediatric medicinal product development. A harmonised approach to the appropriate use of extrapolation from adult data aims to improve the speed of access to new drugs for children.

- ✧ The Assembly adopted the E11A Concept Paper outline at its meeting in Montreal in June 2017, following which an informal WG worked to finalise the Concept Paper and Business Plan which were then endorsed by the ICH Management Committee in October 2017.
- ✧ The Assembly appointed FDA, US as Rapporteur.

3.4.3. Process Refinement & Strategic Themes

Further to the conduct of the new topic selection process in 2017 which resulted in the recommendation to the Assembly of 2 topic proposals, the process was further refined in 2017 by the ICH Management Committee ahead of the 2018 cycle. Additionally, the ICH Management Committee further clarified in 2017 the procedure related to the linkage between Reflection Papers and individual new topic proposals and supported planning of future new topics organised by theme.

The ICH Management Committee also agreed to hold an interim meeting of its New Topics Subcommittee in 2018 to facilitate timely communication with the Assembly on new topic proposals and also agreed to provide the Assembly all proposals submitted, along with the ICH Management Committee's considerations forming the background to the prioritisation of each topic.

3.4.4. Other New Harmonisation Activities

In 2017, the following additional new harmonisation activities received the support of the Assembly and/or ICH Management Committee:

- ✧ **Q3C(R7) Maintenance EWG: Maintenance of the Guideline for Residual Solvents:** The Assembly endorsed the ICH Management Committee recommendation for the EWG to develop Permitted Daily Exposures (PDEs) for the following three proposals: 2-methyltetrahydrofuran, cyclopentylmethylether, and tert-butanol.
- ✧ **Standing Paediatric EWG:** The ICH Management Committee supported establishing a Standing Paediatric EWG to act as a continuous resource available for expert consultation and guidance to other WGs charged with developing new or revised Guidance which may be of relevance to paediatric drug development.

3.5. Implementation of ICH Guidelines

The aim and intention is that **all ICH Regulators should implement all ICH Guidelines**. At the time of Membership application to ICH, each Regulator is expected to have implemented the **ICH Q1, ICH Q7 and ICH E6 Guidelines “Tier 1” ICH Guidelines** and have specific plans with identified milestones and timeframes for implementation of the following **“Tier 2” ICH Guidelines** within the next five years: **E2A, E2B, E2D, M4 (CTD) and M1 (MedDRA)**. The other, remaining ICH Guidelines should be implemented in the near term and as soon as possible.

During 2017, implementation activity by ICH Regulatory Members was high, with **Step 5 (implementation)** of the ICH process being **reached 27 times** for new and existing ICH Guidelines by both new and old ICH Members.

ICH Guideline implementation information (both on final implemented ICH Guidelines and draft ICH Guidelines undergoing public regulatory consultation) is published on the ICH website www.ich.org under each ICH Guideline section for Founding and Standing Regulatory Members. Information from new Regulatory Members will be added in 2018 following work by the ICH Secretariat in 2017 to compile information from new Regulatory Members in a tabulated format for easy consultation by the Assembly and ICH Management Committee.

To further facilitate the goal of enabling the **Assembly to monitor ICH Guideline implementation and the progress of international harmonisation**, and to achieve a common understanding on the meaning of implementation, the following activities received the support of the Assembly and/or ICH Management Committee in 2017:

- ✧ The ICH Management Committee supported the creation of an **Implementation Subcommittee**, to work in particular on the definition of the different levels of implementation, and potential metrics that could be used to monitor the implementation of ICH Guidelines.
- ✧ The Assembly supported an **ICH-driven survey on ICH Guideline implementation** to be led by an independent third party.
- ✧ The ICH Management Committee agreed that the Implementation Subcommittee also work on defining the scope of an ICH-driven implementation survey.

3.6. Training on ICH Guidelines

ICH recognises that training is important to the successful and consistent implementation of ICH Guidelines globally.



3.6.1. ICH Training Strategy

In 2017, work was further progressed by an ICH Management Committee Training Subcommittee on an ICH training strategy, with launch of a **pilot programme** in partnership with a small group of training providers. This work is considered important to ensure **high quality training** is available based upon the scientific and regulatory principles outlined in ICH Guidelines to facilitate the goal of achieving **global harmonised implementation of ICH Guidelines**.

2017 saw close to **10 training courses** conducted by training providers in accordance with **ICH established Terms of Reference**. Training providers selected on the basis of ICH established selection criteria included: **DIA** (Drug Information Association); **RAPS** (Regulatory Affairs Professionals Society); **NEU** (Northeastern University); **Duke-NUS** (Duke University – National University of Singapore); **Harvard MRCT** (Multi-Regional Clinical Trials) Center; and **AHC** (APEC Harmonization Center).

The following decisions were taken by the Assembly and/or ICH Management Committee in 2017 in relation to this work:

- ✧ The ICH Management Committee supported Terms of Reference for the training pilot and eligibility criteria for the selection of training providers.
- ✧ The ICH Management Committee supported the use of a **new logo “ICH Recognised Training Programme”** to be made available to training providers for use on training programmes having the support of the Training Subcommittee following signature of a disclaimer provided by the ICH Secretariat.
- ✧ Following the successful running of the pilot, the Assembly and ICH Management Committee in November 2017 supported continuing work with the training partners of the pilot in accordance with Revised Terms of Reference.
- ✧ The Assembly and ICH Management Committee also supported the development of online training programmes and continued **focussing of the training strategy on Tier 1 and Tier 2 ICH Guidelines**.
- ✧ The Assembly supported the allocation of funds in the budget for training purposes for the next 5 years.

3.6.2. Training Materials Developed by ICH Working Groups

Support was also provided by the Assembly and ICH Management Committee in 2017 for several WGs to develop training materials to help **assist understanding of new concepts** and implementation of their respective ICH Guidelines.

In 2017, the following received the support of the Assembly and/or ICH Management Committee:

- ✧ **ICH E17 Guideline – General Principles for planning and Design of Multi-Regional Clinical Trials:** Following adoption of the final ICH E17 Guideline by the Assembly under *Step 4* in November 2017, the ICH Management Committee gave agreement in principle for the EWG to be converted to an IWG for training purposes

and tasked the EWG with developing a Concept Paper with this focus for approval by the ICH Management Committee in early 2018.

- ✧ **ICH E9(R1) Draft Guideline – Addendum: Statistical Principles for Clinical Trials:** Accompanying endorsement by the Assembly under *Step 2a/b* of the draft Guideline Addendum in August 2017, the ICH Management Committee supported that the EWG develop a **communication video** to present the Estimand concept and agreed the allocation of a small budget for this purpose from the overall training budget.

3.6.3. Working Group Step 2/Step 4 Presentations

In line with ICH procedures, when an ICH Guideline reaches *Step 2b* or *Step 4* of the ICH process, each ICH WG develops a presentation to be included by the ICH Secretariat in a **library of presentations and implementation materials** made available on the ICH website.

In 2017, the ICH Secretariat updated the ICH website accordingly with the presentations developed by WGs who reached *Step 2b* or *Step 4*.

3.7. **MedDRA Activities**

MedDRA, the **Medical Dictionary for Regulatory Activities**, is a rich and highly specific standardised medical terminology developed by ICH to facilitate sharing of regulatory information internationally for medical products used by humans. It is used for **registration, documentation and safety monitoring of medical products** both before and after a product has been authorised for use.



2017 was a successful year of continued growth and development of MedDRA which now has **over 5,000 subscribing organisations in 110 countries worldwide**.

3.7.1. Overview of 2017 MedDRA Management & Key Decisions

Up until November 2017, both a MedDRA Management Board and MedDRA Management Committee ran in parallel, following which MedDRA's formal ownership was assigned to the ICH Association from IFPMA (as trustee of the former International Conference on Harmonisation Steering Committee) and the MedDRA Management Board, established under the former ICH, ceased to operate.

Prior to this assignment, the MedDRA Management Board was responsible for overseeing the main activities of the MSSO (Maintenance and Support Services

Organisation) in 2017, as well as providing oversight and direction to the MedDRA Secretariat. The MedDRA Management Board also addressed the necessary legal and fiscal matters along with the ICH Management Committee and Secretariat to enable the transfer of MedDRA, as part of the overall transfer of ICH assets, from IFPMA to the new ICH Association. Prior to the assignment, the MedDRA Management Committee was responsible only for MedDRA matters related to the new ICH Association, but subsequently it fully assumed all MedDRA management responsibilities.

The following key decisions were taken in 2017 related to MedDRA's management:

Financial:

- ✧ The MedDRA Management Board approved the report of the **MSSO Financial Audit** for the years 2015 and 2016 which was conducted by an international auditing firm under the direction of the MedDRA Management Board.
- ✧ The MedDRA Management Committee approved the **2018 MSSO Subscription fees** for presentation to the Assembly as part of the 2018 Budget for its approval, with the granting of a **5% reduction** for the 2018 subscription rates for lower-revenue users (commercial levels 0 to 2A).
- ✧ The MedDRA Management Committee approved the **2018 MSSO Business Plan**, as well as the **2018 Budget** for presentation to the Assembly for approval.

Operational:

- ✧ In November 2017, the MedDRA Management Committee **unanimously elected** Ms. Sophie Sommerer (Health Canada, Canada) as its Chair to serve for a 1-year term.
- ✧ The MedDRA Management Committee provided its support for the MedDRA Secretariat to proceed with implementing an updated **trademark strategy** for the MedDRA name mark and the MedDRA logo (device) mark in consideration of factors, including the expanded global use of MedDRA.

MSSO/JMO Sub-Licensing Agreement:

- ✧ The MedDRA Management Committee approved amendment of the sub-licensing agreement between MSSO/JMO (Japanese Maintenance Organisation) for sign-off by MSSO and JMO. The amendment provides alignment with the new contract between the ICH Association and the MSSO Contractor to come into effect upon the transfer of MedDRA's ownership to ICH from IFPMA.
- ✧ In line with the sub-licensing agreement between MSSO/JMO, the MedDRA Management Board in discussion with the Japanese Management Board agreed the annual 2017 fee to be paid by JMO to the MSSO.

Facilitating Global Use of MedDRA:

- ✧ The MedDRA Management Board provided its support for the development of a Russian MedDRA translation in coordination with Roszdravnadzor, Russia with development of the translation by a translation firm under the MSSO, with review and input into the translation by Roszdravnadzor, Russia.
- ✧ The MedDRA Management Committee agreed the provision of MSSO local support in countries and regions with an increasing number of subscribers, namely the Republic of Korea and Central America in 2018, and China in 2019, which

will see MSSO providing in-country/region MedDRA experts who speak the local language.

- ✧ The MedDRA Management Committee oversaw work by the MedDRA Secretariat to arrange the transfer in November 2017 of copyright in a **new Korean MedDRA translation** from MFDS, Republic of Korea who had taken the lead to develop this new translation which is planned for release to all MedDRA users by early 2019.

Development of SMQs:

- ✧ The MedDRA Management Board approved **2 new Standardised MedDRA Queries (SMQs)** – the SMQ Dehydration and the SMQ Infective pneumonia, and **four new level 4 SMQs** in the SMQ Malignancies for release to MedDRA users. The addition of these new SMQs result in a **total of 102 SMQs** developed to-date by a CIOMS WG on SMQs.
- ✧ The MedDRA Management Committee supported the renewal for another year of the Memorandum of Understanding ICH has with the CIOMS to develop SMQs.
- ✧ The MedDRA Management Committee reflected on the future of SMQ development in consideration that the majority of common medical concepts have already been developed as SMQs, and provided its support for a pilot of a new approach for ad hoc SMQ development involving the seeking of input on new SMQ requests from the ICH MedDRA Points to Consider (PtC) WG on whether to progress any requests as SMQs.

3.7.2. Oversight of 2017 MedDRA MSSO Activities

A summary is provided as follows on the main activities of the MSSO related to MedDRA development and support of MedDRA users in 2017, which were overseen up until November by the MedDRA Management Board, and thereafter by the MedDRA Management Committee:

- ✧ Conduct of **over 90 training courses** for MSSO MedDRA users, including regulators, with **over 3,000 people trained** via webinars, as well as **63 face-to-face training courses** provided in multiple locations worldwide, including Brazil, Canada, China, Europe, Japan (via the JMO), Mexico, Russia and the United States.
- ✧ **Cooperation with the WHO and its Collaborating Centre, the Uppsala Monitoring Centre (UMC)** resulting in joint MSSO MedDRA and UMC WHODrug User Group meetings in India (February 2017), in China (September 2017), and a MedDRA presentation at the 2017 WHO Annual Meeting of National Pharmacovigilance Centres (NPCs) in Uganda (November 2017).
- ✧ Participation in the **Innovative Medicines Initiative's WEB-RADR (Recognising Adverse Drug Reactions) project** to develop and test a set of **“patient friendly terms”** in MedDRA to support direct patient reporting of adverse events through mobile applications and web portals which will be published on the MedDRA website www.meddra.org.

- ✧ Liaison with the **International Medical Device Regulatory Forum (IMDRF)** regarding consideration on the terminology to be used for device adverse event reporting. The MSSO attended meetings of the IMDRF Adverse Event Terminology and Coding WG in June and November 2017 to share information on MedDRA.
- ✧ Support of the work of the **ICH M1 PtC WG** to (i) update with each MedDRA release the PtC documents on Term Selection and Data Retrieval and Presentation, (ii) develop a **condensed version of the PtC documents** which could be easily translated in languages where a MedDRA translation exists, and (iii) develop a **companion document to the PtC documents**.
- ✧ Provision of assistance to Regulators expressing interest in MedDRA or working towards a MedDRA translation in their national language.
- ✧ Consolidation of all four **MedDRA Best Practice documents** into a single document available in all 11 MedDRA translation languages.
- ✧ Achievement of **ISO 9001:2015 certification**, following transition from the 2008 ISO standard.
- ✧ Release of an **Account Self-Service Application** to allow MSSO Subscribers to retrieve subscription information and passwords, confirm the subscription status of business partners, and obtain certificates for attending face-to-face training classes.

4. 2017 Overview of Meetings & Planning

4.1. 2017 Meetings

In 2017, ICH activities were progressed via face-to-face meetings and teleconferences. ICH's biannual meetings see the meeting of WGs for 4-6 days in parallel of Assembly, ICH Management Committee and MedDRA Management Committee meetings, and are important for progressing ICH's work.

2017 meeting locations were particularly noteworthy, being the **first time** that ICH meetings were held outside the host countries/regions of the Founding ICH Members. The first meeting of the year took place in **Montreal, Canada** on 27 May to 1 June, and the second meeting in **Geneva, Switzerland** on 11 to 16 November, with ICH Standing Regulatory Members Health Canada, Canada and Swissmedic, Switzerland playing an important role in ensuring the smooth running of meetings in their respective countries. With ICH's growing Membership and Observership, close to **400 experts** attended each of the meetings.

The reports of [Assembly](#) and [ICH Management Committee](#) face-to-face meetings and teleconferences from 2017 are made available on the **ICH website**.

Details on 2017 meetings are provided as follows:

Assembly Meetings

- ✧ The **Assembly met twice during 2017**, at the time of ICH's biannual meetings: on 31 May to 1 June and on 15 to 16 November.
- ✧ The Assembly was chaired in 2017 by Mrs. Lindström-Gommers (EC, Europe Chair) and Dr. Tominaga (MHLW/PMDA, Japan, Vice-Chair) who were elected in October 2015 for a 2-year term. Mrs. Lindström-Gommers and Dr. Tominaga were **re-elected unanimously** by the Assembly at the November 2017 meeting to serve a second 2-year term.



ICH Assembly, Montreal June 2017



ICH Assembly, Geneva November 2017

ICH Management Committee Meetings

- ✧ The ICH Management Committee met several times throughout the year:
 - o **12 times via teleconference** on the following dates: 13 February, 9 March, 29 March, 13 April, 16 May, 6 September, 25 September, 26 September, 3 October, 17 October, 31 October, and 13 December.
 - o **2 face-to-face** during ICH's biannual meetings in June and November.
- ✧ The ICH Management Committee was chaired in 2017 by Dr. Mullin (FDA, US, Chair) and Dr. Tominaga (MHLW/PMDA, Japan, Vice Chair). Dr. Mullin and Dr. Tominaga were **re-elected unanimously** by the ICH Management Committee at the November 2017 meeting to serve a second 1-year term.

MedDRA Management Committee Meetings

- ✧ The MedDRA Management Committee met several times:
 - o **3 times via teleconference** on 3 April, 27 September, and 18 December.
 - o **2 times face-to-face** during ICH's biannual meetings on 27 to 28 May and 11 to 12 November.
- ✧ In view of a temporary arrangement until such time as the MedDRA Management Committee would become fully operational, Health Canada, Canada acted as Chair, with Ms. Sommerer in the lead and being supported by Ms. Morrison.

- ✧ With the MedDRA Management Committee becoming fully operational in November 2017, Ms. Sommerer was **unanimously elected** by the MedDRA Management Committee as Chair for a 1-year term.

ICH Working Group Meetings

A total of **13 WGs met face-to-face** at each of the biannual meetings in 2017 and are detailed in Annex VI.

4.2. Planning of Future ICH Meetings

In 2017, the ICH Management Committee took decisions regarding the organisation of future ICH meetings. **Key decisions** are outlined below:

- ✧ The ICH Management Committee supported **Kobe, Japan** as the location for the June 2018 meeting to be hosted by MHLW/PMDA, Japan and JPMA.
- ✧ The ICH Management Committee approved FDA, US and PhRMA as the hosts of the November 2018 meeting to be held in the **US**.
- ✧ The ICH Management Committee agreed to an **interim meeting** of its Subcommittees to take place in March 2018 in London, hosted by EC, Europe at the European Medicines Agency office.
- ✧ The ICH Management Committee took a decision to contract a **Professional Conference Organiser** (PCO) for the organisation of future ICH meetings starting in June 2019 and supported the organisation in 2017 of a request for proposals under the leadership of its Financial Subcommittee and with the support of the ICH Secretariat with a view to selecting a PCO to contract.

5. 2017 ICH Operational Matters

5.1. ICH Articles & Procedures

5 Documents support the governance of the ICH Association and were each updated in 2017 in view of experience gained with the operation of the new ICH Association: the ICH Articles of Association, the Assembly Rules of Procedures (RoP), the ICH Management Committee RoP, the MedDRA Management Committee RoP and the Standard Operating Procedures (SOPs) for the ICH WGs. Each of these documents is available on the [ICH website](#).

The following highlights the key decisions taken in 2017 regarding these documents.

ICH Articles of Association

- ✧ The Assembly approved several refinements to the ICH Articles of Association in May 2017 which included: revisions to the criteria for international organisations to become Observers; changes to manage the size of delegations to ICH meetings; and a reduction of the term in office for Elected ICH Management Committee Representatives from 4 to 3 years in order to facilitate rotation.

- ✧ The ICH Management Committee also supported that the Secretariat print the Articles in a booklet form for distribution to Assembly participants at the November meeting.

Assembly RoP

- ✧ The Assembly approved amendments to the Assembly RoP in May 2017, including several reflecting changes also made to the ICH Articles of Association. Changes included: revisions to the criteria for international organisations to become Observers; changes related to manage the size of delegations to ICH meetings; clarifications regarding the Assembly Chair and Vice Chair role; adjustment of procedures related to minutes and press releases; as well as other changes for clarity and consistency.

ICH Management Committee RoP

- ✧ The ICH Management Committee approved several updates to their RoP in 2017. In May 2017, changes approved included those reflecting changes made to the ICH Articles of Association in May 2017, such as revision to the term in office for an Elected ICH Management Committee Representative, as well as: an adjustment of procedures related to minutes and summary reports; further clarification on the use of the ICH logo; and other changes for clarity and consistency. The RoPs were further revised in November to clarify use and translation of the ICH Member logo. And in December, changes were made to clarify the eligibility criteria for Elected ICH Management Committee Representatives further to discussion with the Assembly at the Geneva meeting in November 2017.

MedDRA Management Committee RoP

- ✧ The MedDRA Management Committee approved minor changes to its RoP in August 2017 to clarify procedures related to MSSO and JMO participation to MedDRA Management Committee meetings, as well as rotation of Chairmanship under the temporary arrangement until the MedDRA Management Committee would become fully operational.

SOPs for the ICH Working Groups

- ✧ The ICH Management Committee approved 2 versions of the SOPs for WGs in 2017. Version 3.0 in May and Version 4.0 in November 2017. Version 3.0 included clarifications on the attendance of support staff to face-to-face meetings, sign-off procedures, and the maintenance procedure. And included provisions to clarify the relevant expertise of prospective WG experts, a procedure for appointing experts to WGs, appointment of Ad-hoc Observers to WGs, and a policy on the publication of papers or presentations related to the work of WG. Version 4.0 included further clarifications regarding: appointment of additional staff and support staff; publication of the membership of EWGs/IWGs on the ICH website; process for appointment of Regulatory Chair and Rapporteur; confidentiality considerations; revisions to

Business Plan and Work Plan templates; and other changes for consistency with the Assembly RoP.

5.2. ICH Funding

ICH Financial Audit

In line with the ICH Articles of Association, the Assembly took the decision in 2016 to appoint Moore Stephens Refidar SA for an initial period of 2 years to audit the annual financial statements of the ICH Association. The audit of the first financial period (23 October 2015 to 31 December 2016) was conducted in 2017. In June 2017, the **Assembly approved the audited accounts** of the ICH Association for this first period and the auditor's consideration that the statements complied with Swiss law and the ICH's Articles of Association. Furthermore, the Assembly approved the overall closing statement of ICH's 2016 financial activities, taking into account a consolidated view of information from the new ICH Association and activities via IFPMA as trustee of the former ICH Steering Committee, pending completion of the transfer of ICH assets.

Tax Exemption

In October 2017, in view of ICH's standing as a **non-profit Swiss Association** in line with its Articles of Association, ICH was granted a tax exemption by the Geneva tax authorities making it exempt from Geneva cantonal and Swiss federal tax.

ICH Funding

In line with the ICH Articles of Association, 2017 remained a second transitional year for the ICH Association, where the ICH Management Committee ensured the funding of the ICH Association, ahead of the implementation starting in 2018 of Membership Fees for all ICH Members in line with the decision taken by the Assembly in 2016.

In 2017, ICH Membership Fees were payable according to Table 1 below:

Membership Category	Membership Fee (CHF / Swiss Franc)
Founding Regulatory Member	CHF 233,000
Founding Industry Member	CHF 233,000
Standing Regulatory Member	CHF 96,000
Regulatory Member	N/A in 2017 <i>(to start in 2018)</i>
Industry Member	N/A in 2017 <i>(to start in 2018)</i>
Standing Observer	N/A
Observer	N/A

Table 1: 2017 Membership Fees

In May 2017, the **Assembly approved a provisional 2018 ICH Budget, and in November approved a revised 2018 ICH Budget** covering additional costs including those related to major upgrades to the ICH websites; ICH logo (device) trademark

registration; Secretariat travel to the interim ICH Management Committee meeting; funding of the ICH meeting reception; and an additional Secretariat staff of 1 FTE to account for the growing need of ICH for Secretariat support in particular for training activities.

MedDRA Funding

MedDRA activities are self-financed through the collection of annual subscription fees from organisations which are subscribers to MedDRA.

- ✧ In November 2017, the **Assembly approved the 2018 MedDRA Budget**, which included a **5% reduction** for the 2018 MSSO MedDRA Subscription fees for users of Commercial levels 0 to 2A, on the basis of a recommendation from the MedDRA Management Committee. (See also Section 3.7 above on MedDRA Activities.)

5.3. Asset Transfer

On 10 November 2017 an important step was taken in fully operationalizing the new ICH Association, with the ICH Management Committee providing its support for the **completion of the transfer of assets to the ICH Association from IFPMA as trustee of the former ICH (International Conference on Harmonisation) Steering Committee**. With the completion of the transfer, ownership in assets including MedDRA, funds and contracts passed to the ICH Association, paving the way for the undertaking of follow-up administrative steps by the ICH Secretariat, such as the seeking of trademark assignments with the competent trademark authorities in each of the jurisdictions where a MedDRA trademark had been registered by IFPMA in its capacity as trustee. (See also Section 5.7 below on ICH Secretariat Activities.)

5.4. ICH Communication

In 2017, work was progressed in view of further **enhancing communication and transparency with stakeholders** on ICH activities, with the following important steps taken by the Assembly and/or ICH Management Committee:

- ✧ The ICH Management Committee agreed the **publication on the ICH website of the names of all active EWG/IWG experts**, along with the names of each EWG/IWG's Regulatory Chair and Rapporteur. Inclusion of a disclaimer was also supported by the ICH Management Committee to clarify that experts are appointed by their nominating ICH Member or Observer party and are responsible for representing the views of that party, which may not necessarily reflect their personal views.
- ✧ The ICH Management Committee supported an **ICH Transparency Policy**, which included publication on the ICH website of a set of Q&As on transparency on a new [transparency page](#), as well as publication of **photographs and biographies** of the Member Representatives and Observer Delegates of the ICH Management Committee, MedDRA Management Committee and Assembly, as well as those of ICH Coordinators and the ICH Secretariat.

- ✧ The ICH Management Committee furthermore supported that consideration be given to **Training and Stakeholder needs** at the outset of any new ICH harmonisation topic, with approval of a recommendation from its Communication Subcommittee to add a new section on this in the Concept Paper and Business Plan templates.
- ✧ These plans and others were supported by the Assembly along with a **2017-2018 Communication and Stakeholder Engagement Plan**.

ICH Regional Public Meetings

While ICH no longer organises the large international ICH Conferences that it did between 1991 and 2003, public meetings are still considered important for disseminating information of ICH activities. ICH Members periodically hold **dedicated ICH regional public meetings**, either independently or in collaboration with other non-profit organisations. Information on these meetings is made available by the ICH Secretariat on the ICH website. It should be noted, that in addition to these regional public meetings, ICH Members were also active in finding opportunities to present on ICH and its Guidelines in other fora in 2017.

In 2017, Members held the following ICH regional public meetings:

Brazil

ANVISA, Brazil organised a meeting in July 2017 to raise awareness of stakeholders in Brazil of its ICH membership and the process of implementation of the ICH Guidelines.

Japan

JPMA in collaboration with MHLW/PMDA, Japan organised ICH regional public meetings in Japan on 30 June and 15 December to report from the preceding ICH meetings.

United States & Canada

Health Canada, Canada and the FDA, US held joint public meetings ahead of each of the 2017 ICH meetings. The first was held in Silver Spring, MD, US on 24 April to which participants were also able to participate by webcast. The second was held in Ottawa, Canada on 19 October.

5.5. Elected ICH Management Committee Representatives

In accordance with the ICH Articles of Association, the intent was for the **ICH Management Committee to open to membership** from Elected ICH Management Committee Representatives by 1 January 2018. Following discussion at the November 2017 meeting, the Assembly agreed to postpone the election until the next Assembly meeting in June 2018 in acknowledgement of the need for the **eligibility criteria to be further clarified**. Subsequently, the ICH Management Committee started revising its RoP in order to clarify the notion of a “good record of implementation” which is stated in both the Assembly and ICH Management Committee RoP as a prerequisite for eligibility

as an Elected ICH Management Committee Representative. The revised ICH Management Committee RoP were adopted in December 2017 with this clarification.

5.6. Cooperation with the IPRP

In 2017, the Assembly and ICH Management Committee gave support for the ICH Secretariat to provide **support services to the IPRP (International Pharmaceutical Regulators Programme)** to be funded by ICH Regulatory Members, starting from January 2018 which will be conducted and financed separately from the support of ICH activities. The IPRP is a consolidation of the International Generic Drug Regulators Programme (IGDRP) and the International Pharmaceutical Regulators Forum (IPRF) involving many of the drug regulatory authorities already involved in ICH. IPRP is a venue promoting regulatory cooperation and convergence but also for discussions amongst regulators on ICH Guideline implementation.

5.7. ICH Secretariat

Staffing

The following highlights key points and decisions related to ICH/MedDRA Secretariat staffing in 2017:

- ✧ Secretariat staffing was planned at **6 FTEs (Full Time Equivalents) for 2017** (compared with 4.8 FTE in 2016), allocated between support for ICH activities (4.2 FTEs) and MedDRA activities (1.8 FTEs). The Secretariat however operated at less than full capacity in 2017, with approximately 5 FTEs over the full year, due to delays in the hiring of new staff, staff leave and staff departures.
- ✧ The year saw the hiring of Dr. Véronique Kuntzelmann in January, who filled until November 2017 the Manager position left vacant end of 2016 by Dr. Sarah Adam, and the hiring of Dr. Anne Latrive in May, in a **newly created Manager position** approved by the ICH Management Committee aimed at increasing the capacity of the ICH Secretariat in view of new tasks including the provision of support to the IPRP (see Section 5.6 above).
- ✧ In November 2017, the ICH Management Committee supported **additional resources** be allocated to the ICH Secretariat to account for the growing need for Secretariat support of the training activities and other new activities assigned to the ICH Secretariat, and agreed to add 1 FTE from 2018 to enable the ICH Secretariat to support these activities.

Support of Asset Transfer and Operationalising the ICH Association

In 2017, work was progressed by the ICH Secretariat under the direction of the ICH Management Committee and MedDRA Management Committee to complete the transfer of assets from IFPMA as trustee of the former ICH (International Conference on Harmonisation) Steering Committee, and towards making the ICH Association fully

operational. The ICH Secretariat was supported in this work by external advisors, including legal and fiscal advisors.

Furthermore, in view of the completion of the asset transfer and fully operationalising the new ICH Association, both the ICH Management Committee and MedDRA Management Committee approved an **additional signatory** from the ICH Secretariat, Ms. Emilie Macara, to provide representation vis-à-vis third parties on ICH and MedDRA related matters. It was agreed that Ms. Emilie Macara, along with existing signatories: Mrs. Lenita Lindström-Gommers (EC, Europe); Dr. Toshiyoshi Tominaga (MHLW/PMDA, Japan); and Dr. Dawn Ronan (ICH Secretariat) have joint (by two) signatory rights to represent the ICH Association as authorized persons. Changes to the signatory rules in the ICH Employee Handbook were also made.

Considerable work has been undertaken in order to prepare for the asset transfer which was finally completed in November 2017 thus rendering the ICH Association fully independent. The following represents a list of key activities undertaken in 2017 in support of work to complete this asset transfer and make the ICH Association fully operational:

- ✧ Liaison with the Geneva tax authorities in follow-up of ICH's request for a tax exemption (granted in October 2017) and submission of the ICH Association's **first tax return** to the Swiss Federal Tax Administration in September 2017.
- ✧ **Registration of the ICH Association to the Swiss VAT**, with submission of first quarterly VAT declarations to the Swiss VAT authority.
- ✧ Assessment of the value of assets to be transferred from IFPMA to ICH.
- ✧ **Finalisation of asset transfer agreement documents** and organisation of sign-offs by IFPMA, ICH and third parties.
- ✧ **Contracting of a fiduciary services firm** to assist the ICH Secretariat with the management of ICH accounts in line with generally accepted Swiss accounting principles, as well as other financial activities such as payments and payroll preparation.
- ✧ Undertaking the necessary steps for the ICH Association to **"hire" the ICH Secretariat staff** whose contracts were transferred from IFPMA upon completion of the asset transfer, including: requesting work permits; setting tax at source payments; and affiliating ICH with an organisation with responsibilities for payment to the Swiss authorities of the statutory social deductions.
- ✧ **"Transferring" ICH Secretariat staff pensions** under the same terms, by affiliating the ICH Association and its staff with the same pension fund used to-date by the staff when at IFPMA.
- ✧ **Work with an insurance broker to assess options for insurances** the ICH Association should have for itself and its staff, many of which are mandatory, with contracts put in place as of the transfer date for the following insurances:
 - o Office content insurance

- o Professional civil responsibility insurance
- o Travel insurance
- o Loss of earnings in case of sickness insurance
- o Professional accident insurance
- o Supplemental accident insurance
- ✧ **Taking the necessary steps with the bank** to add Ms. Emilie Macara as a new ICH signatory, and to acquire credit cards in accordance with the terms of use;
- ✧ Initiation of **new office search** following completion of asset transfer, with steps taken towards the **set-up of new office IT infrastructure** e.g., purchase of server etc...

2017 Day-to-Day Management Key Activities

The ICH Secretariat is liaising with the ICH Management Committee Chair/Vice-Chair and/or the ICH Assembly Chair/Vice-Chair particularly on important issues. The following outlines key activities undertaken by the ICH Secretariat in 2017, many of a routine nature, in accordance with its responsibilities for the day-to-day management of ICH and coordinating ICH activities including the provision of support to the Assembly, the ICH Management Committee, its WGs and the MedDRA Management Board/Committee:

- ✧ **Preparation of agenda papers and reports** for the biannual face-to-face meetings of the Assembly, the ICH Management Committee and the MedDRA Management Board/Committee in Montreal, Canada in May/June 2017 and in Geneva, Switzerland in November 2017, as well as for the following **teleconferences** which were organised by the Secretariat in 2017: **12** ICH Management Committee teleconferences; **2** ICH Coordinator teleconferences; and **3** ICH MedDRA Management Board/Committee teleconferences.
- ✧ Supporting ICH harmonisation activities and the work of **24 ICH WGs** in 2017, including keeping up-to-date membership lists and establishing 2 new Expert WGs in 2017.
- ✧ Administration of the ICH website including:
 - **Keeping the ICH website up-to-date** with publication of draft documents for public consultation, *Step 2* and *Step 4* presentations, Press Releases, regional public consultation dates and guideline implementation dates.
 - **Implementing changes in line with the communication plans** supported by the Assembly and/or ICH Management Committee, including publication of: EWG/IWG membership lists; photographs and biographies of Assembly and ICH Management Committee Member Representatives and Observer delegates; and increased content, in line with the approved transparency policy, as well as photographs.
 - **Launching a new working area** for Assembly Members and managing this and the other existing working areas for the ICH Management Committee, MedDRA Management Committee/MedDRA Management Board and ICH WGs.

- **Development of a website upgrade and maintenance plan** including a proposed consolidation of all websites under the same Content Management System for cost-related and efficiency purposes, and implementation of a web statistics and analytical tool, which was approved by the ICH Management Committee in 2017, with the MedDRA Management Committee also approving plans related to MedDRA websites.
- ✧ **Responding to stakeholder enquiries** received via the ICH mailbox with input solicited as necessary from ICH experts and ICH Coordinators, and which in 2017 represented close to 200 enquiries.
- ✧ **Drafting ICH Association Reports and Work Plans** in support of ICH Management Committee and MedDRA Management Board/Committee reporting to the Assembly, including: 2016 Annual Report; 2018 ICH Work Plans and ICH Multi-Annual Strategic Plan; and 2018 MedDRA Work Plans.
- ✧ **Provision of support and input for the work of the ICH Management Committee Subcommittees** on: Financials; Training; Communication; Standard Operating Procedures for WGs; Membership; and New Topics.
- ✧ **Financial administration**, including: drafting of 2018 ICH and MedDRA budgets and multi-year budget plans; preparation of closing reports; organising the first financial audit; and managing ICH's grant agreement with FDA (in 2017 this included submissions of: quarterly Federal Financial Report, the annual Research Performance Progress Report, a request for the delay in the drawing of funds pending the transfer of assets from IFPMA to the ICH Association, and drawing of funds in December 2017 following the completion of the transfer).
- ✧ **Updating of ICH's agreement with Health Level Seven** which was supported for sign-off by the ICH Management Committee.
- ✧ **Contract management**, including those related to day-to-day operations (e.g., website hosting and maintenance), as well as support of the MedDRA Management Board/Committee's oversight of the MSSO Contractor, including the organisation in 2017 of a Financial Audit of the MSSO.
- ✧ **Development of a strategy regarding trademark registration** of the ICH logo (device) which was approved by the ICH Management Committee in November 2017, and of the MedDRA logo (device) and name, which was approved by the MedDRA Management Committee in December 2017.

Annex I

Assembly Member Representatives & Observer Delegates

December 31, 2017

Founding Regulatory Members

EC, Europe

Mrs. Lenita Lindström-Gommers (*Chair*)
Dr. Tomas Salmonson
Dr. Georgios Balkamos

MHLW/PMDA, Japan

Dr. Toshiyoshi Tominaga (*Vice Chair*)
Dr. Nobumasa Nakashima
Mr. Naoyuki Yasuda

FDA, US

Dr. Theresa Mullin
Ms. Joan Wilmarth Blair

Founding Industry Members

EFPIA

Dr. Sabine Luik
Mr. Pär Tellner

JPMA

Dr. Hironobu Hiyoshi
Dr. Masafumi Yokota

PhRMA

Mr. Jerry Stewart
Dr. Peter Honig

Standing Regulatory Members

Swissmedic, Switzerland

Dr. Petra Doerr
Ms. Cordula Landgraf

Health Canada, Canada

Ms. Catherine Parker
Dr. Celia Lourenco

Regulatory Members

ANVISA, Brazil

Ms. Patrícia Pereira Tagliari
Ms. Tatiana Cambraia Sa Lowande

CFDA, China

Mr. Xiaoling Qin
Mr. Siyuan Zhou

HSA, Singapore

Dr. Dorothy Toh
Ms. Chua Siew Wei

MFDS, Republic of Korea

Dr. Sun Hee Lee
Dr. Won Sik Lee

Industry Members

BIO

Ms. Lila Feisee
Dr. Wassim Nashabeh

IGBA

Dr. Nick Cappuccino
Ms. Beata Stepniewska

WSMI

Ms. Caroline Mendy
Dr. Gerald Dziekan

Standing Observers

WHO

Mr. Mike Ward
Dr. Samvel Azatyan

IFPMA

Mr. Thomas B. Cueni
Dr. David Jefferys

Observers

CDSCO, India

Dr. S. Eswara Reddy

CECMED, Cuba

Dr. Celeste Sánchez González

COFEPRIS, Mexico

Dr. Mario Alanis Garza

INVIMA, Colombia

Mr. Javier Humberto Guzmán Cruz

MCC, South Africa

Dr. Jeanette Lotter

National Center, Kazakhstan

Mrs. Aliya Kessikova

Roszdrazhnadzor, Russia

Dr. Sergey Glagolev

TFDA, Chinese Taipei

Ms. Chao-Yi Wang

TGA, Australia

Dr. Kaylene Raynes

APEC

Dr. Young Ju Choi

ASEAN

Ms. Charunee Krisanaphan

EAC

Mr. John Patrick Mwesigye

GHC

Dr. Hajed M. Hashan

PANDRH

Ms. Analía Porrás

SADC

Mrs. Fortunate Ntombi Fakudze

APIC

Mrs. Marieke van Dalen

CIOMS

Dr. Lembit Rägo

EDQM

Dr. Susanne Keitel

IPEC

Ms. Janeen SkutnikWilkinson

PIC/S

Mr. David Churchward

USP

Dr. Kevin Moore

Annex II

ICH Management Committee Representatives

December 31, 2017

Founding Regulatory Members

EC, Europe

Ms. Lenita Lindström-Gommers
Prof. Spiros Vamvakas

MHLW/PMDA, Japan

Dr. Toshiyoshi Tominaga (*Vice Chair*)
Dr. Nobumasa Nakashima
Mr. Naoyuki Yasuda

FDA, US

Dr. Theresa Mullin (*Chair*)
Ms. Joan Wilmarth Blair
Ms. Pujita Vaidya

Founding Industry Members

EFPIA

Dr. Sabine Luik
Mr. Pär Tellner

JPMA

Dr. Hironobu Hiyoshi
Dr. Masafumi Yokota

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Mr. Jerry Stewart
Dr. Peter K. Honig

Standing Regulatory Members

Swissmedic, Switzerland

Dr. Petra Doerr
Ms. Cordula Landgraf

Health Canada, Canada

Ms. Catherine Parker
Dr. Celia Lourenco

Standing Observers

WHO

Mr. Mike Ward
Dr. Samvel Azatyan

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Mr. Thomas B. Cueni
Dr. David Jefferys

Annex III

MedDRA Management Committee Representatives

31 December 2017²

Founding Regulatory Members

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Dr. Sabine Brosch

MHLW/PMDA, Japan

Mr. Hideo Eno
Mr. Takayuki Okubo

FDA, US

Ms. Mary Ann Slack
Dr. Christopher Jankosky

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EFPIA

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Dr. Christina Winter

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Mr. Yo Tanaka
Ms. Yoko Hattori

PhRMA

Dr. Peter K. Honig
Ms. Camille Jackson

Standing Regulatory Member

Health Canada, Canada

Ms. Heather Morrison
Ms. Sophie Sommerer

MHRA UK

Mr. Mick Foy
Mr. Philip Tregunno

WHO Observer Delegate

WHO

Dr. Daisuke Tanaka
Mr. Mike Ward

² The representation on the MedDRA Management Committee and MedDRA Management Board was equivalent in 2017.

Annex IV

ICH Secretariat Staff

31 December 2017

Director

Dr. Dawn Ronan

Managers

Dr. Isabelle Güller

Dr. Anne Latrive

Coordinators

Ms. Coralie Angulo

Ms. Emilie Macara

Annex V

Assembly Member ICH Coordinators

31 December 2017

Founding Regulatory Members

EC, Europe

Dr. Georgios Balkamos
Dr. Milton Bonelli (Technical
Coordinator)

MHLW/PMDA, Japan

Mr. Fumihito Takanashi
Ms. Chieko Hirose (Technical
Coordinator)

FDA, US

Ms. Amanda Roache
Dr. Michelle Limoli (Technical
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JPMA

Mr. Mitsuo Mihara

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Ms. Camille Jackson

Standing Regulatory Members

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Ms. Cordula Landgraf

Health Canada, Canada

Mr. Nick Orphanos

Regulatory Member

ANVISA, Brazil

Ms. Ana Carolina Moreira Marino Araujo

CFDA, China

Dr. Wei Zhou

HSA, Singapore

Ms. Chua Siew Wei

MFDS, Republic of Korea

Ms. Pan Soon Kim

Industry Members

BIO

Ms. Lila Feisee

IGBA

Dr. Shinichiro Hirose

WSMI

Ms. Caroline Mendy

Annex VI

ICH Working Groups which met face-to-face at ICH's biannual meetings in 2017

Montreal, Canada in 27 May – 1 June

Group Code	Topic	Meeting Days
S1(R1) EWG	Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals	4 days
S5(R3) EWG	Revision on Detection of Toxicity to Reproduction for Medicinal Products & Toxicity to Male Fertility	5 days
S11 EWG	Nonclinical Safety Testing in Support of Development of Paediatric Medicines	4 days
Q11 IWG	Q&As on Selection and Justification of Starting Materials for the Manufacture of Drug Substances	4 days
Q12 EWG	Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management	5 days
E9(R1) EWG	Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses	4 days
E11(R1) EWG	Addendum to Paediatric Drug Development	4 days
E17 EWG	Multi-Regional Clinical Trials	4 days
E19 EWG	Optimization of Safety Data Collection	4 days
E2B(R3) EWG/IWG	Revision of the Electronic Submission of Individual Case Safety Reports	4 days
M2 EWG	Electronic Standards for the Transfer of Regulatory Information	4 days
M9 EWG	Biopharmaceutics Classification System-based Biowaivers	4 days
M10 EWG	Bioanalytical Method Validation	4 days

Geneva, Switzerland in 11 – 16 November

Group Code	Topic	Meeting Days
E2B(R3) EWG/IWG	Revision of the Electronic Submission of Individual Case Safety Reports	4 days
E8(R1) informal WG	Revision of General Considerations for Clinical Trials	4 days
E9(R1) EWG	Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses	5 days
E17 EWG	Multi-Regional Clinical Trials	4 days
E19 EWG	Optimization of Safety Data Collection	4 days
Paediatric Extrapolation Informal WG	Paediatric Extrapolation Informal WG	4 days
M1 PtC WG	MedDRA Points to Consider WG	3 days
M2 EWG	Electronic Standards for the Transfer of Regulatory Information	5 days
M8 EWG/IWG	The Electronic Common Technical Document: eCTD	4 days
M9 EWG	Biopharmaceutics Classification System-based Biowaivers	4 days
M10 EWG	Bioanalytical Method Validation	4 days
Q3D(R1) Maintenance EWG	Maintenance of the Guideline for Elemental Impurities	4 days
S11 EWG	Nonclinical Safety Testing in Support of Development of Paediatric Medicines	4 days

Annex VII

Overview of harmonisation activities and accomplishments in 2017

Topic Code	Type of Working Group	Topic Name	Accomplishments	Anticipated Milestones (at the end of 2017)
E2B(R3)	EWG/IWG	Revision of Electronic Submission of ICSRs	Reached <i>Steps 3 and 4</i> in June 2017 of additional Q&As in Implementation Guide Package and agreed Code List #26. Reached <i>Steps 3 and 4</i> in November 2017 for EDQM Dose Form and Route of Administration Term User Guide and agreed Code Lists #9 and #14	N/A (Ongoing Activity)
E8(R1)	EWG	Revision of ICH Guideline on General Considerations for Clinical Trials	New topic approved for harmonisation in June 2017 – Activities progressed in line with Concept Paper/Business Plan/Work Plan	<i>Steps 1 and 2</i> are expected by early 2019
E9(R1)	EWG	Addendum to Defining Appropriate Estimand for a Clinical Trial/Sensitivity Analyses	Reached <i>Steps 1 and 2a/b</i> in August 2017	<i>Steps 3 and 4</i> are expected in June 2019
E11(R1)	EWG	Addendum to Pediatric Drug Development	Reached <i>Steps 3 and 4</i> in August 2017	Activity Completed Standing Paediatric EWG established

Topic Code	Type of Working Group	Topic Name	Accomplishments	Anticipated Milestones (at the end of 2017)
E11A	EWG	Pediatric Extrapolation	New topic approved for harmonisation in June 2017 – Activities progressed in line with Concept Paper/Business Plan/Work Plan	<i>Steps 1 and 2a/b</i> are expected in November 2020
E14/S7B	Discussion Group	Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	Activities progressed in line with Concept Paper/Business Plan/Work Plan	N/A (Ongoing Activity)
E17	EWG	ICH Guideline on Multi-Regional Clinical Trials	Reached <i>Steps 3 and 4</i> in November 2017	Activity Completed IWG to be established to work on training materials and Q&As
E18	EWG	ICH Guideline on Genomic Sampling and Management of Genomic Data	Reached <i>Step 3</i> in August and <i>Step 4</i> in September 2017	Activity Completed
E19	EWG	ICH Guideline on Optimization of Safety Data Collection	Activities progressed in line with Concept Paper/Business Plan/Work Plan	<i>Steps 1 and 2a/b</i> are expected in November 2018

Topic Code	Type of Working Group	Topic Name	Accomplishments	Anticipated Milestones (at the end of 2017)
Q3C(R7)	Maintenance EWG	Maintenance of the Guideline for Residual Solvents	Progressed work to develop Permitted Daily Exposure (PDE) levels for 3 new solvents adopted in Jun2 2017: 2-methyltetrahydrofuran, cyclopentylmethyleher and tert-butanol	(Ongoing Activity) <i>Step 1</i> and <i>2</i> are expected by June 2018 for 3 new solvents
Q3D(R1)	Maintenance EWG	Maintenance of the Guideline for Elemental Impurities	Progressed work on Addendum to Q3D Guideline to include PDEs for cutaneous and transdermal products and work on revision of Cadmium inhalation PDE A minor error correction was undertaken to remove a reference to a missing document in Module 8 of the Training package	(Ongoing Activity) <i>Step 1</i> and <i>2</i> are anticipated by November 2018 for Addendum and June 2018 for the Cadmium inhalation PDE
Q11	IWG	Q&As on API Starting Materials	Reached <i>Steps 3</i> and <i>4</i> in August 2017	Development of training materials to be undertaken
Q12	EWG	ICH Guideline on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management	Reached <i>Steps 1</i> in June and <i>2a/b</i> in November 2017	<i>Steps 3</i> and <i>4</i> are expected by June 2019

Topic Code	Type of Working Group	Topic Name	Accomplishments	Anticipated Milestones (at the end of 2017)
M1	PtC WG	MedDRA Points to Consider	Updated the two Points to Consider (PtC) documents on Term Selection and Data Retrieval and Presentation with MedDRA release versions 20.0 & 20.1. Progressed development of Companion Document.	N/A (Ongoing Activity)
M2	EWG	Electronic Standards for the Transfer of Regulatory Information	Progressed development of project opportunities proposals, including development of a concept proposal on CeSHarP - Clinical electronic Structured Harmonized Protocol agreed for submission to the Assembly as a new topic in line with the new topic process Finalised new PDF Specification.	N/A (Ongoing Activity)
M7(R1)	Maintenance EWG	Addendum to Assessment and Control of DNA Reactive Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk	First Addendum reached <i>Steps 3 and 4</i> in June 2017	Second Addendum expected to reach <i>Step 1</i> and <i>Step 2a/b</i> in 2018

Topic Code	Type of Working Group	Topic Name	Accomplishments	Anticipated Milestones (at the end of 2017)
M8	EWG/IWG	Electronic Common Technical Document: eCTD	Reached <i>Step 3</i> and <i>4</i> of eCTD v3.2.2 Q&A v1.30 and Study Tagging Files (STF) Stylesheet v2.3 in August 2017. Reached <i>Step 3</i> and <i>4</i> of eCTD v4.0 Change Request/Q&A document v1.1 in November 2017.	N/A (Ongoing Activity)
M9	EWG	Biopharmaceutics Classification System-based Biowaivers	Activities progressed in line with Concept Paper/Business Plan/Work Plan	<i>Steps 1</i> and <i>2a/b</i> are expected by June 2018
M10	EWG	Bioanalytical Method Validation	Activities progressed in line with Concept Paper/Business Plan/Work Plan	<i>Steps 1</i> and <i>2a/b</i> are expected by November 2018
S1	EWG	Revision of Rodent Carcinogenicity Studies for Human Pharmaceuticals	Activities progressed in line with Concept Paper/Business Plan/Work Plan	<i>Steps 1</i> and <i>2a/b</i> are expected by June or November 2019
S3A	IWG	Q&As on Note for Guidance on Toxicokinetics	Reached <i>Steps 3</i> and <i>4</i> in November 2017	Activity Completed

Topic Code	Type of Working Group	Topic Name	Accomplishments	Anticipated Milestones (at the end of 2017)
S5(R3)	EWG	Revision on Detection of Toxicity to Reproduction for Medicinal Products and Toxicity to Male Fertility	Reached <i>Step 1</i> in June and <i>Step 2a/b</i> in August 2017	<i>Steps 3 and 4</i> are expected in late 2019
S9	IWG	Q&As on Nonclinical Evaluation for Anticancer Pharmaceuticals	Activities progressed in line with Concept Paper/Business Plan/Work Plan	<i>Steps 3 and 4</i> are expected by June 2018
S11	EWG	ICH Guideline on Nonclinical Safety Testing - Paediatric Medicines	Activities progressed in line with Concept Paper/Business Plan/Work Plan	<i>Step 1</i> and <i>Step 2a/b</i> expected in June 2018