ICH
harmonisation for better health

ICH Association

2023 Annual Report

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

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Approved by the ICH Assembly on 4 June 2024

Ms. Lenita Lindström
ICH Assembly Chair
EC, Europe

Dr. Gabriela Zenhäusern
ICH Assembly Vice Chair
Swissmedic, Switzerland

Message from Assembly Chair and Vice Chair

It is with great pleasure that we look back at the ICH Association's collective achievements over the past year.

Throughout 2023, our collaborative efforts have been focused on driving progress in regulatory harmonisation. Notably, work on the revision of the ICH E6 Guideline has seen significant momentum. This pivotal guideline revision aims to further strengthen clinical trials and modernise clinical trial conduct, ultimately benefitting patients and stakeholders across the globe.

Our commitment to global harmonisation is exemplified by the continued expansion of ICH membership. We are delighted to report the addition of NAFDAC, Nigeria as a new regulatory authority from Africa as Observer, as well as the inclusion of EDA, Egypt as our first Regulatory Member from Africa. Additionally, the completion of the Arabic translation of MedDRA, in addition to many other languages, contributes to advancing harmonisation efforts worldwide.

As we reflect on the accomplishments detailed within this report, we extend our sincere gratitude to all our colleagues and stakeholders for their unwavering support and dedication to our shared mission, and we look forward to the impactful work that lies ahead.

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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 contribute 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.

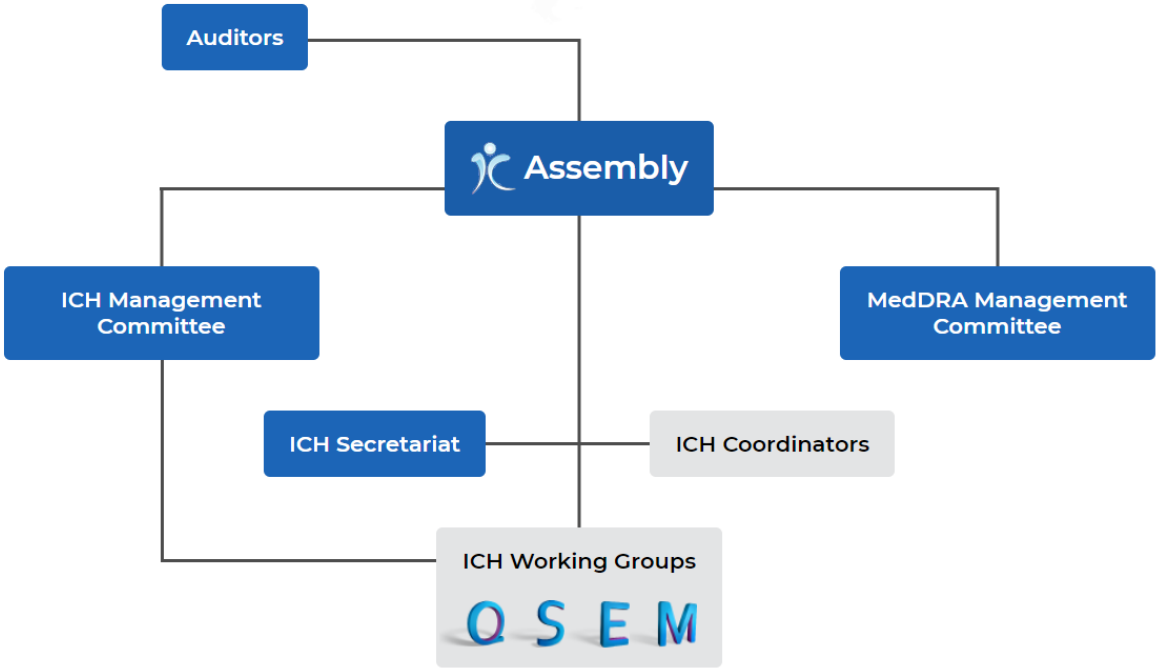
The **ICH's aims** are the following:

- 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 adequate **implementation and integration of common standards** through the dissemination of, the communication of information about and coordination of training of 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, 2023 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 ICH Management Committee may set up **Subcommittees** for dealing with specific topics to assist the Management Committee. In 2023 the following Subcommittees were supporting the work of Management Committee: Finance, New Topics, and Training. The full list of the ICH Management Committee Member Representatives and Observer Delegates as of December 31, 2023 is provided in Annex II.

MedDRA Management Committee

- 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, 2023 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 ICH Secretariat is responsible for the implementation of the decisions of ICH's governing bodies. Actions taken by the ICH Secretariat in this regard in 2023 are referred to in Section 5.7.
- The full list of ICH Secretariat Staff as of December 31, 2023 is provided in Annex IV.

Auditors

- In 2022, the Assembly agreed to re-appoint Moore Stephens Refidar SA for a further period of 2 years to audit the **annual financial statements** of the ICH Association for 2022 and 2023.

ICH Coordinators

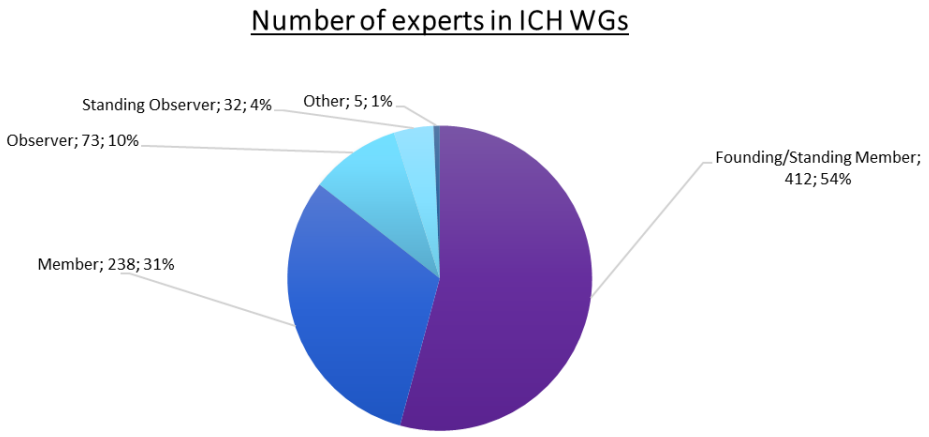
- **Fundamental to the smooth running of ICH** has been the designation of an ICH Coordinator per ICH Member and Standing Observer to act as the main contact point with the ICH Secretariat. Coordinators ensure proper distribution of ICH documents to the appropriate persons from their organisation and 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, 2023 is provided in Annex V.

2. 2023 Overview of ICH Membership & Observership

2.1. Continued Expansion of ICH Membership & Observership

A driving factor of ICH's 2015 organisational change was to make ICH a **truly global initiative** and enable an expanded forum for dialogue on scientific issues between regulatory authorities and the pharmaceutical industry on the harmonisation of the technical requirements for pharmaceuticals products. The year 2023 saw the addition of 1 new Member and 2 new Observers, bringing ICH to a total of **21 Members and 37 Observers**. By the end of 2023 over 1,100 individuals were contributing to the work of ICH, either as Representatives/delegates of ICH bodies, experts on WGs or in supporting roles.

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 2023 these WGs involved the participation of **over 700 technical experts**.



Overview of Expert Participation in ICH, as of October 2023

Further to the ICH Management Committee's decision taken in 2019 to enable the establishment of a Plenary Working Party (PWP) for each new WG established, at the end of 2023 PWPs had been established for 8 WGs (ICH E2D(R1), E6(R3), E20, M4Q(R2), M12, M15, Q1/Q5C, Q3E). This allows interested ICH Members and Observers without an expert in the WG to follow more closely work on ICH Guidelines and to be consulted ahead of *Step 1* and *Step 3* sign-offs. The establishment of PWPs has been welcomed by ICH's Membership and Observership as a way to enable wider involvement, whilst maintaining the efficiency of the process.

2.2. New Members and Observers Approved in 2023

At the meeting in Vancouver, Canada in June 2023, the Assembly approved EDA, Egypt as a **new ICH Regulatory Member**, in addition to one **new ICH Regulatory Observer**: NAFDAC, Nigeria, while at the meeting in Prague, Czech Republic in November 2023, the Assembly welcomed PPBHK, Hong Kong, China as a **new ICH Regulatory Observer.**

3. 2023 ICH Harmonisation Activities

A major output of ICH's work, in line with the specific aims of the organisation, is the development by WGs of **harmonised technical guidelines** and other work products to support harmonisation activities on **Q**uality, **S**afety **E**fficacy and **M**ultidisciplinary topics.

In 2023, these activities were progressed on **33 topics** by technical WGs [including Expert Working Groups (EWG), Implementation Working Groups (IWG) and Discussion Groups (DG)], with support from the ICH Secretariat and under the oversight of the ICH Management Committee, with reporting to the Assembly. These activities were undertaken mostly via email and teleconferences.

The **key outcomes in 2023** relating to ICH harmonisation efforts include the following documents, available on the ICH website:

- Completion at ***Step 4*** of the ICH process and **finalisation** of work (please see Section 3.1) on:
  - **2 New Guidelines** – Q14, S12
  - **4 Revised Guideline** – Q2(R2), Q5A(R2), Q9(R1), M7(R2)
  - **1 New Addendum to a Guideline** – M7(R2) Addendum
  - **1 Updated Q&A document** – E2B(R3)

- Reaching of ***Step 2a/b*** of the ICH process and completion of drafts (please see Section 3.2) of:
  - **1 Revised Guideline –** E6(R3) Principles and Annex 1

- **3 New Topics** were approved in 2023 (see Section 3.3) – E22, M16, S13

An overview of all ICH WG activities and accomplishments in 2023 is presented in Annex VI.

3.1. ICH Guidelines & Other WG Work Products Finalised in 2023

Please note that all ICH documents referenced below can be found on the ICH website at ich.org.

ICH Q2(R2) Guideline - Validation of Analytical Procedures

Steps 3 and 4 for the ICH Q2(R2) Guideline were reached in November 2023.

This revised Guideline includes validation principles that cover analytical use of spectroscopic or spectrometry data, some of which often require multivariate statistical analyses and continues to provide a general framework for the principles of analytical procedure validation applicable to products mostly in the scope of Q6A and Q6B. In addition, with ICH Q14 the Q2(R2) Guideline complements ICH Q8 to Q12 and ICH Q13 for Continuous Manufacturing.

ICH Q9(R1) Guideline - Quality Risk Management

Steps 3 and *4* for the ICH Q9(R1) Guideline were reached in January 2023.

This revised Guideline is intended to provide guidance on the principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality.

ICH Q5A(R2) Guideline - Viral Safety Evaluation of Biotechnology Products Derived from Cell lines of Human or Animal Origin

Steps 3 and *4* for the ICH Q5A(R2) Guideline were reached in November 2023.

This revised Guideline retains key principles of the original Guideline and provides additional recommendations on the established and complementary approaches to control the potential viral contamination of biotechnology products.

ICH Q14 Guideline - Analytical Procedure Development

Steps 3 and *4* for the ICH Q2(R2) Guideline were reached in November 2023.

The new Guideline harmonises the scientific approaches of Analytical Procedure Development and provides the principles relating to the description of Analytical Procedure Development process. It intends to improve regulatory communication between industry and regulators and facilitate more efficient, sound scientific and risk-based approval as well as post-approval change management of analytical procedures.

ICH S12 Guideline - Nonclinical Biodistribution Considerations for Gene Therapy Products

Steps 3 and *4* for the ICH Q2(R2) Guideline were reached in March 2023.

This new Guideline is intended to provide guidance on the conduct of nonclinical biodistribution (BD) studies in the development of gene therapy (GT) products that mediate their effect by the expression (transcription or translation) of transferred genetic materials, and harmonised recommendations to facilitate the development of GT products while avoiding unnecessary use of animals, in accordance with the 3Rs (reduce/refine/replace) principles.

ICH E2B(R3) Q&As – Electronic Transmission of Individual Case Safety Reports (ICSRs)

Steps 3 and *4* for the ICH E2B(R3) Q&As Version 2.4 were reached in January 2023.

ICH M7(R2) Guideline and Addendum – Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

Steps 3 and 4 for the ICH M7(R2) Guideline and the accompanying M7(R2) Addendum on *"Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes"* were reached in April 2023. The two documents were published alongside the M7(R2) Q&As, which were adopted in 2022.

3.2. ICH Guidelines Endorsed at Step 2a/b in 2023

In 2023 the following ICH Guideline was endorsed at ***Step 2a*** of the ICH process by all Members of the Assembly, in parallel with the 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 E6(R3) Guideline (Principles and Annex 1) - Good Clinical Practice (GCP)

Steps 1 and *2a/b* were reached for the revised draft Guideline in May 2023.

The revised draft Guideline is composed of principles and annexes that expand on the principles with specific details for different types of clinical trials. The draft Guideline applies to interventional clinical trials of investigational products that are intended to be submitted to regulatory authorities and may also be applicable to other interventional clinical trials of investigational products that are not intended to support marketing

authorisation applications in accordance with local requirements. Annex 1 which is included in the S*tep 2* draft Guideline is intended to provide information on how the concepts can be appropriately applied to clinical trials.

3.3. New Harmonisation Activities

3.3.1. Approval of New Topics

In 2023 the ICH Management Committee and its New Topics Subcommittee assessed **7 New Topic proposals** which had been submitted by ICH Members and Observers by a mid-December 2022 deadline as part of the call welcoming topics in Efficacy, Multidisciplinary and Safety topic areas where work could start immediately upon topic selection, and excluding Quality topics from the scope, in view of the number of currently approved or ongoing Quality topics.

Further to this, an assessment **of all proposals** was prepared for the Assembly, and the ICH Management Committee provided its recommendation for **New Topic proposals**.

Based on the ICH Management Committee assessment, the Assembly approved the following 3 new harmonisation activities:

General Considerations for Patient Preference Studies

This new ICH Efficacy Guideline provides considerations for a systematic approach to designing, conducting, analysing and presenting Patient Preference Studies, when studies are considered important to be conducted to supplement information about the assessment of a product or inform drug development and related decisions.

- The E22 informal WG will be established with a delayed start in early 2024 to initiate work in Q2 2024.

Nonclinical Safety Studies for Oligonucleotide-based Therapeutics

This new ICH Safety Guideline clarifies regulatory expectations on nonclinical safety evaluation of various Oligonucleotide-based treatment options by providing a common understanding of the applicable requirements.

- The S13 informal WG will be established with a delayed start in June 2024.

Bioequivalence for Modified-Release Products

This new ICH Multidisciplinary Guideline represents an important next step for harmonisation of bioequivalence standards for more complex dosage forms, with several elements being harmonised under the M13 series of Guidelines, which are currently under development being transferrable to this new guideline.

- The M16 informal WG will be established with a delayed start to initiate work in June 2025, after the ICH M13C draft Guideline will have reached *Step 2.*

In addition, the Assembly decided to progress a new ICH Reflection Paper titled “Pursuing Opportunities for Harmonisation in Real-World Data to Generate Real-World Evidence with a Focus on Effectiveness of Medicines”. The paper, which presents opportunities for development of new ICH Guidelines, was made available on the ICH website for public

consultation in June 2023 until September 2023. Following revision based on the comments received during the public consultation, the tentative date for finalisation of the Reflection Paper is June 2024.

3.3.2. Other New Harmonisation Activities

In 2023, work on other new harmonisation activities included the finalisation of Concept Papers for the following topics:

- ICH Q2(R2)/Q14 IWG **"Validation of Analytical Procedures and Q14: Analytical Procedure Development**".
- ICH Q5A(R2) IWG **"Viral Safety Evaluation of Biotechnology Products Derived from Cell lines of Human or Animal Origin**".
- ICH Q13 IWG **"Continuous Manufacturing of Drug Substances and Drug Products**".
- ICH Q9(R1) IWG **"Quality Risk Management**".
- ICH E6(R3) Annex 2 EWG Sub-group **"Guideline for Good Clinical Practice Annex 2".**
- ICH E21 EWG **"Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials**".
- ICH S1B(R1) IWG **"Testing for Carcinogenicity of Pharmaceuticals".**

In addition, the ICH M2 Two-Dimensional (2D) Barcode Recommendation v1.0 was finalised by the M2 EWG and endorsed by the Assembly in September 2023.

3.4. Implementation of ICH Guidelines

At *Step 5* of the ICH process, harmonised ICH Guidelines are implemented by ICH Regulatory Members and Observers within their respective country/region. This is in line with the ICH Articles of Association and the aim and intention that **all ICH Regulatory Members should implement all ICH Guidelines**. At the time of Membership application to ICH, each Regulator is expected to have implemented the **"Tier 1" ICH Guidelines**: **Q1, Q7 and E6,** 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.

ICH Guideline implementation information is published on the ICH website ich.org, with a searchable database tool and periodically updated by the ICH Secretariat which allows information on the status of implementation of any ICH Guideline by any ICH Regulatory Member to be readily retrieved by all stakeholders.

Monitoring the progress of international harmonisation and coordinating efforts in this regard is an important ICH focus. ICH is working to understand the level of implementation and adherence to ICH Guidelines within Regulatory Member and Observer countries/regions. In support of this effort, an **ICH-driven survey** was developed in 2023 for the third time in coordination with the Centre for Innovation in Regulatory Science

(CIRS), an independent third party contracted by ICH to conduct the survey, to be launched early January 2024. The objective of the study is principally to assist the ICH Management Committee in determining whether Regulatory Members would meet the eligibility criteria for the Management Committee elections in 2024 and to also allow participating Observers interested in future ICH Membership to reference survey findings. The scope of the survey included Tier 1 ICH Guidelines for Observers; Tier 2 and Tier 3 ICH Guidelines for ICH Non-Founding Non-Standing Regulatory Members, based on the criteria of ICH Membership and MC Elections; and 7 newer Tier 3 Guidelines for Founding and Standing Regulatory Members to identify regulatory training and capacity building needs. The results of the study are to be presented at the ICH meeting in June 2024.

3.5. Training on ICH Guidelines

As part of its effort to achieve **global harmonised implementation of ICH Guidelines,** ICH is working on ensuring that high quality training is available based upon scientific and regulatory principles outlined in the ICH Guidelines. Training materials developed by/with ICH can be accessed with the respective ICH Guideline on the ICH website, as well as in the Training Library which serves to re-group all training materials in one location.

3.5.1. ICH Training Strategy

In an effort to ensure the availability of high-quality training on ICH Guidelines, work in 2023 included **financial support of training on ICH Guidelines** organised by ICH Regulatory Members and Observers; work with **ICH Training Associates** as part of a multi-year strategic plan to develop online training materials for all ICH Guidelines, in addition to offering tailored training; and the development of training materials by **ICH Working Groups.**

In addition, in 2023 the work was progressed on the following key areas for improvement of ICH training processes / activities, identified in December 2022: renovation and organisation of the ICH Training Website; development of a training evaluation process; and assessment of needs / benefits of the ICH Training Subcommittee outputs.

Progress was made in 2023 in particular on the following deliverables:

- Ongoing development of an interactive training web page and infographic for onboarding new ICH Members and Observers to be finalised in 2024;
- Launch in August 2023 of a pilot evaluation process, for Regulators participating on a voluntary basis, of in-person and hybrid regulatory trainings co-funded by ICH, and progress on identifying tools to evaluate ICH online training materials, including materials developed by ICH WGs and Training Associates;
- Launch of a Survey on ICH Training Needs between July - September 2023 among all ICH Regulatory Members and Observers, as well as Industry Trade Associations (on a voluntary basis), with an objective to inform the development of criteria and prioritisation of training needs related to content and/or implementation of ICH Guidelines, with 17 high priority needs identified based on both Regulatory and Industry feedback.

ICH Training Associates:

Further to the endorsement by the Assembly in November 2021 of a **multi-year training approach** including a 5-year budget plan (2022-2027) and support of the general concept of ICH training on specific Guidelines resulting in contracting 3 Training Associates (2 new organisations and 1 already contracted) in 2022, the work was progressed on the development of the training on the following Guidelines:

- ICH E2;
- ICH E8(R1);
- ICH E6(R3);
- ICH E17;
- ICH Q3 series;
- ICH Q5 series;
- ICH Q8-12.

In addition, Q1 Stability Guidelines in-depth training modules developed by one Training Associate were published on the ICH website in February 2023, and ICH M4 Common Technical Document introductory overview video developed by another Training Associate, was finalised and published in March 2023.

The continued aim of the ICH Training Associates programme is **to assist ICH in its efforts to address in a strategic manner the training needs of its Regulatory and Industry Members and Observers**, and in order to achieve this aim the Management Committee supported the need for additional Training Associates based upon the ICH Survey on training needs results to be further considered in 2024.

ICH Regulatory Training

2023 also saw the ICH Management Committee approve the **provision of ICH funding support to training programmes on ICH Guidelines organised by 5 ICH Regulatory Members and 1 ICH Regulatory Observer.** This came further to a Call for Expression

of Interest launched by the ICH Management Committee in December 2022 and saw support provided for training planned by:

- ANPP, Algeria: Quality of Biological Products;
- EDA, Egypt: Training on Quality Guidelines;
- Health Canada, Canada: ICH E19 Implementation Training;
- MHLW/PMDA, Japan: The 5th ICH Forum: ICH Quality Guideline Update;
- NMPA, China: Training on ICH E19 Guideline;
- SFDA, Saudi Arabia: Safety Considerations for Human Medicines.

In addition, the following training approved in 2021, and postponed due to the COVID-19 pandemic took place in 2023:

- JFDA, Jordan: JFDA, Jordan Regulatory Updates Overview.

3 other trainings approved in 2020 and 2022, which were initially postponed to 2023, were also further delayed and may be postponed to 2024, and one other training approved in 2022 has been withdrawn by the applicant. The ICH Assembly approved carry-over in the 2024 ICH budget to potentially support these postponed training events in 2024.

In 2023, the Regulatory Training Funding Process has been updated ahead of the launch of the 2024 call for expressions of interest, to include an evaluation survey to be completed by the organiser upon completion of the training.

3.5.2. Training Materials Developed by ICH Working Groups

Further to support provided by the Assembly and ICH Management Committee for WGs to pursue training material development to help **assist understanding of new concepts** and implementation of their respective ICH Guidelines, in 2023 work was finalised on developing training materials on the following ICH topics, with the assistance of Founding Regulatory Member FDA, United States which made available the support of its studios for the production of videos:

- E2B(R3);
- E6(R3).

Additionally, training materials have been developed by the Q9(R1) EWG to support the implementation of the ICH Q9(R1) Guideline.

Working Groups *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 on the ICH website. In 2023, the following presentations were made available:

- ICH E6(R3) *Step 2* Presentation;
- ICH M13A *Step 2* Presentation;
- ICH M7(R2) Guideline & Addendum *Step 4* Presentation;

- ICH M7(R2) Q&As *Step 4* Presentation;
- ICH Q9(R1) *Step 4* Presentation;
- ICH Q13 *Step 4* Presentation;
- ICH S12 *Step 4* Presentation.

3.6. 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.

Having gained over 600 new subscribers since the start of the year, the MedDRA user community, in 137 countries, is growing. The continued growth is a clear indicator of the successful adoption of MedDRA over the past 24 years as a worldwide standard in the protection of public health.

2023 saw further expansion in the support provided to facilitate the use of MedDRA in a broader set of countries/regions. With the goal of ensuring MedDRA's continued responsiveness to the needs of global MedDRA users, MedDRA is now available in 21 languages, with the release of Arabic in January, Estonian in September and Finnish in December 2023.

Continued MedDRA training and helpdesk support in 2023 was assisted by local support staff in Europe, Russia, India, China, Republic of Korea, Latin America, the United States of America and other regions.

3.6.1. Overview of 2023 MedDRA Management & Key Decisions

The MedDRA Management Committee is responsible for overseeing the main activities of the MSSO (Maintenance and Support Services Organisation), as well as providing oversight and direction to the "MedDRA Secretariat" which is provided by the ICH Secretariat. (MedDRA Secretariat implementation of key MedDRA Management Committee decisions are referred to in Section 5.5 below.)

The following key decisions were taken in 2023 related to MedDRA's management:

Financial:

- The MedDRA Management Committee supported the **2024 Budget** including the **2024 MSSO Subscription Fees,** subsequently approved by the Assembly. The Subscription Fees included a 10% decrease in 2024 MedDRA MSSO subscription

rates across all levels, with an additional redefining of the subscription levels which will allow a number of Level 3 subscribers to now obtain a Level 2 subscription.

- The MedDRA Management Committee approved the **2024 MSSO Business Plan**.

Operational:

- The MedDRA Management Committee supported the **2024 Annual MedDRA Management Committee Work Plan** for submission to the Assembly, which was subsequently approved by the Assembly.
- The MedDRA Management Committee in 2023 oversaw the conduct of and approved the report from a **MSSO Financial Audit** of the years 2020, 2019, 2018 and 2017. It also supported a further **MSSO Financial Audit** in 2024 of the years 2021, 2022 and 2023 as well as the re-engagement of the MedDRA Management Committee Audit Sub-group to advance additional audits, in view of the MedDRA Management Committee's multi-year audit plan covering the clinical-quality-procedural and IT audits, and the identification of the approach/auditors.
- The MedDRA Management Committee supported the continued implementation of a **MedDRA trademark strategy** by the MedDRA Secretariat for the registration of the MedDRA name mark and the MedDRA logo (device) mark in new ICH Member/Observer countries/regions as ICH grows. In 2023, this included filing for registration in Tunisia, as well as providing oversight and input on trademark follow-ups.
- The MedDRA Management Committee provided support for the release of new translations of MedDRA in the following languages: Arabic, Estonian and Finnish.
- The MedDRA Management Committee supported further enhancement of **MSSO local in-country/in-region support**, including training and helpdesk services, with agreement taken to extend support with addition of specific support for Brazil (with a Brazilian Portuguese Speaker) and addition of local support for Africa/Middle East (with an Arabic Speaker), noting that in 2023, in-person training events were resumed globally.
- The MedDRA Management Committee elected Dr. Barbee Whitaker (FDA, United States) to serve as the MedDRA Management Committee Chair for a two-year term and Dr. Craig Simon (Health Canada, Canada) to serve the remaining period of the term of the previous Vice-Chair i.e. one-year term.
- The MedDRA Management Committee also further pursued the assessment of MedDRA **business continuity** in various scenarios, to ensure the current high level of functionality which MedDRA users have come to expect.
- The MedDRA Management Committee approved revisions to the MedDRA Management Committee RoP to enable WHO Observer participation in all MedDRA Management Committee Sessions.

Development of SMQs:

- Further to the support of the MedDRA Management Committee and the MedDRA PtC WG, the new Standardised MedDRA Query (SMQ) "Neurodevelopmental disorders" is currently in development. **110 SMQs are currently in production.**

3.6.2. Oversight of 2023 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 2023, which were overseen by the MedDRA Management Committee:

- Release to users of MedDRA versions 26.0 and 26.1 on 1 March and 1 September 2023 respectively.
- **Trainings** made available in several forms: face-to-face training, webinars and on-demand e-learning. Over 16,000 attendees participated in these trainings from 99 countries.
- Continued work towards the translation of MedDRA into the remaining **languages of the European Economic Area** in collaboration with individual European National Competent Authorities, which includes: Maltese MedDRA translation initiated in 2021; Icelandic and Norwegian MedDRA translations initiated in 2022; and Croatian, Lithuanian and Slovenian initiated in 2023; and Estonian and Finnish translations finalised and released in 2023.
- Maintenance and development of software tools for MedDRA users e.g., Web-based Browser, Desktop Browser, Version Analysis tool etc. In 2023, an important area of work was Application Programming Interfaces (APIs) as well as the exploration of the use of Artificial Intelligence (AI) / Machine Learning (ML).
- Support for **mapping with other terminologies** in 2023: (1) continued work with the International Medical Device Regulators Forum (**IMDRF**) on the maintenance of the mapping between MedDRA and IMDRF's terminology: Annex E: Health Effects – Clinical Signs, Symptoms and Conditions Terms and Codes, an updated version of which was released in March; (2) continued cooperation with **SNOMED International**, on the maintenance and distribution of the bi-directional MedDRA/SNOMED mapping, with an updated mapping released to MedDRA and SNOMED users in May 2023; and (3) the signature of a Project Collaboration Agreement between WHO and ICH on the **MedDRA-ICD 10/11 mappings**.
- Release of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents in March 2023.

4. 2023 Overview of Meetings & Planning

4.1. 2023 Meetings

Starting in March 2023, ICH held in-person meetings of the ICH Assembly, Management Committee, MedDRA Management Committee and ICH WGs.

The reports of Assembly and ICH Management Committee face-to-face meetings and teleconferences from 2023 are made available on the **ICH website**.

Assembly Meetings

- The **Assembly met twice during 2023**, at the time of ICH's biannual meetings: from 12 to 13 June and from 31 October to 1 November.
- Both meetings were chaired by **Ms. Lenita Lindström (EC, Europe, Chair) and Dr. Gabriela Zenhäusern (Swissmedic, Switzerland, Vice-Chair)**.

ICH Management Committee Meetings

- The ICH Management Committee met 3 times **in-person**:
  - Interim Meeting in Lausanne, Switzerland in March 2023
  - ICH Biannual Meeting in Vancouver, Canada in June 2023
  - ICH Biannual Meeting in Prague, Czech Republic in October/November 2023

- The ICH Management Committee also met **virtually** throughout the year:
  - **7 times via teleconferences** held on 6 March, 4 April, 15 May, 31 August, 5 September, 14 September and 10 October.
  - These sessions were well-attended and co-chaired by Dr. Theresa Mullin (FDA, United States, Chair), Dr. Nobumasa Nakashima (MHLW/PMDA, Japan, Vice-Chair until April 2023) and then Mr. Naoyuki Yasuda (MHLW/PMDA, Japan, Vice-Chair).

MedDRA Management Committee Meetings

- The MedDRA Management Committee met several times throughout the year:
  - **6 times via teleconference on** 22 February, 14 March, 19 April, 10 July, 30 August and 26 September 2023.
  - **2 in-person meetings** during ICH's biannual meeting on 12-13 June and 31 October-1 November 2023.
- All meetings in 2023 were chaired by **Mr. Mick Foy (MHRA, UK, Chair)**, and/or **Dr. Barbee I. Whitaker (FDA, United States, Vice-Chair)**.

ICH Working Groups Meetings

The following 13 WGs were supported to meet in-person by the ICH Management Committee in June 2023: E2D(R1); E20; E21; M15; Q1/Q5C; Q2(R2)/Q14; Q5A(R2); E6(R3); E11A; M4Q(R2); M13; Q9(R1) and Q13.

During the second biannual meeting in November 2023 the following 16 WGs met in-person: E2B(R3); E6(R3) Annex 2; E11A; E20; E21; M1 PtC; M4Q(R2); M11; M12; M13; M15; Q1/Q5C; Q2(R2)/Q14; Q3E; Q5A(R2) and Q9(R1).

With support from the ICH Management Committee, 6 WGs also held interim meetings in 2023: E6(R3); Q2(R2)/Q14; M2 (with virtual participation of the M8 subgroup); M4Q(R2); M11 and M12.

Other WGs continued their activities remotely, with meetings in the form of teleconferences.

4.2. Planning of Future ICH Meetings

In 2023, the ICH Management Committee took decisions regarding the organisation of future ICH meetings. **Key decisions** are outlined below:

- The ICH Management Committee agreed on the organisation of an ICH Management Committee Interim Meeting in Lisbon, Portugal from 25 to 26 March 2024.
- The ICH Management Committee agreed to continue planning and organising for its next biannual meeting in Fukuoka, Japan in June 2024.
- The ICH Management Committee agreed on proceeding with the planning of the biannual meeting in Montreal, Canada from 2 – 6 November 2024.
- The ICH Management Committee agreed on the following dates for the 2025 and 2026 meetings:
    - 10 – 15 May 2025 in Europe (location to be confirmed)
    - 1 – 5 November or 15 – 19 November 2025 in Asia (location to be confirmed)
    - 30 May to 3 June 2026 in the Americas (location to be confirmed)
- The ICH Management Committee supported the revision to the SOPs of the WGs to provide for up to 6 interim WG meetings starting from 2025, noting that the number of WGs meeting at the biannual meetings would be limited to up to 12 starting with the second meeting of 2024, and that the request for an interim meeting should be made at least 4 months in advance of the interim meeting. In view of planning already underway for 15 WG meetings at the June 2024 biannual meeting, the number of interim WG meetings would be limited to up to 4 in 2024.

Professional Conference Organizer (PCO)

- The ICH Biannual Meeting in Prague was the first meeting supported by the newly contracted PCO based in Geneva, Switzerland.
- The ICH Management Committee agreed to an amendment of the agreement with the new PCO for providing support with organising the interim meeting in March 2024 in Lisbon, Portugal.

5. 2023 ICH Operational Matters

5.1. ICH Articles & Procedures

5 Documents support the governance of the 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 (SOP) of the ICH WGs. Each of these documents is available on the ICH website.

The following highlights the key decisions taken in 2023 regarding these documents:

ICH Assembly RoP

- The Assembly approved several amendments to the Assembly RoP with approval of version 13.0 in May and 14.0 in October 2023. Amendments related to: inclusion a new

Coordinator Position for ICH Standing Observers and amendments regarding the procedure for notification by Members of any additional participants to ICH meetings.

ICH Management Committee *RoP*

- The ICH Management Committee approved several amendments to its RoP with approval of version 13.0 in June and 14.0 in October 2023, with approval Coordinator Position for ICH Standing Observers and amendments regarding the procedure for notification by Members of any additional participants to ICH meetings.

MedDRA Management Committee RoP

- The MedDRA Management Committee approved version 8.0 at its meeting in October 2023, in order to enable WHO Observer participation in all MedDRA Management Committee Sessions.

SOPs of the ICH Working Groups

- The ICH Management Committee approved version 13.0 in May 2023. Amendments related to: removal of Section 1.4 and reference to the Business Plan and inclusion of a new Annex 10 Final Concept Paper Template incorporating the Business Plan; addition of a new Coordinator position for ICH Standing Observers; update to Annex 8 New Topic Proposal Template; addition of a new Annex 9 Concept Paper Outline; revision of Section 1.4.4 Meeting Attendance including provisions for virtual attendance; and addition of Section 2.4. Minor Revision Procedure describing an abbreviated revision procedure for guidelines.

5.2. ICH Operational Efficiency

In 2023, the ICH Management Committee worked to provide operational support to ICH WGs. This included support for the Threshold Project of the Q3E EWG on Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics and approval to engage 4 external organisations in support of the activities and the generation of PDEs, with the ICH Assembly supporting the allocation of ICH funds for this activity.

The ICH Management Committee also approved documentation in support of the launch of a Request for Proposal (RFP) for Technical Writing support for ICH WGs, with the RFP receiving Management Committee support to launch in November 2023 for a 3-month period.

In addition to its support for the above, the ICH Assembly further supported in 2023 the development of the Plenary Working Party (PWP) enhanced process to provide additional opportunities for PWP participants to observe WG activities, initial internal mapping of existing Implementation WGs to improve ICH processes, and procedural adjustments aimed at enhancing overall efficiency.

5.3. ICH Funding

ICH Financial Audit

In June 2023 **the Assembly approved the 2022 Audited Accounts and Financial Statements of the ICH Association**, supporting their submission along with ICH's 2022 tax return.

ICH Funding[1]

2023 Membership Fees were paid as follows by all ICH Members in line with the decision taken by the Assembly in November 2021, with an increase in fees for non-Founding/non-Sanding Members to CHF 45,000:

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	CHF 45,000
Industry Member	CHF 45,000
Standing Observer	N/A
Observer	N/A

2023 Membership Fees

The Assembly furthermore approved the fees for 2025, which will be kept at the same level as for 2023 and 2024.

In November 2023, the Assembly approved the 2024 ICH Association Budget, and noted the 5-Year budget projection for 2024-2028. Information can be found on the ICH website regarding the 2024 ICH Association Budget and Membership Fees.

MedDRA Funding

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

In October-November 2023, **the Assembly approved the 2024 MedDRA Budget, including 2024 MSSO MedDRA Subscription Fees**, which encompass a 10% discount across all levels, with an additional redefining of the subscription levels allowing a number of Level 3 subscribers to now obtain a Level 2 subscription.

Information can be found on the ICH website regarding the 2024 ICH Association Budget, with information on the MedDRA Subscription Fees available on the MedDRA website.

[1] ICH notes that in lieu of the membership fee payment required of ICH Founding Members, for the period 2016 to-date, FDA, United States has supported ICH through an equivalent level of funding via a grant mechanism. ICH (2016 to-date) is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award [FAIN] totaling $2,494,586 with 11% funded by FDA/HHS, and $22,238,328 and 89% funded by non-U.S. government sources. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

Financial Management

In 2023, the ICH Finance Committee, which includes representation from both ICH and MedDRA Management Committees, provided support for ICH financial management. In addition to support provided in 2023 for 2024 ICH and MedDRA budget preparation and 5-Year ICH and MedDRA budget planning for 2024-2028, the Finance Committee also oversaw the funds placed in line with the asset preservation policy approved and implemented by ICH in 2022 which is aimed at enabling the long term conservation of the total value of ICH reserve funds, in line with ICH's stated purpose of having such funds, to achieve a total net return that is at a minimum equal to the rise of the Consumer Price Index (CPI), thus ensuring that the purchasing power of the reserve funds is maintained over time.

5.4. ICH Communication

The following should be noted in relation to communication activities in 2023:

- Acknowledging the importance of relevant patient stakeholder engagement in ICH and input from the patient community on ICH Guidelines, an ICH session was organised at the DIA Global Annual Meeting at the end of June 2023, in Boston, United States on "ICH Work to Harmonize Requirements for Safe and Effective Medicines: What's in It for Patients?";
- In 2023, the ICH Award for Outstanding Contribution to ICH Harmonisation for Better Health was awarded for the second time to recognise those experts who have made significant and sustained contributions through their leadership roles in developing ICH Guidelines. The ICH Assembly awarded 6 nominees, whose names were published on the ICH website.

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 on ICH activities. ICH Members periodically hold dedicated **ICH regional public meetings**, either independently or in collaboration with other non-profit organisations. In 2023, ICH Members holding regional public meetings were: ANVISA, Brazil; FDA, United States with Health Canada, Canada; and JPMA.
Information on these meetings is made available by the ICH Secretariat on the ICH website.

5.5. Cooperation with the IPRP

Under a Memorandum of Understanding (MoU) between ICH and the IPRP (International Pharmaceutical Regulators Programme), the ICH Secretariat continued in 2023 the provision of support services to the IPRP, which are funded by IPRP Members and conducted separately from the support of ICH activities. IPRP is a venue which addresses the increasingly complex global regulatory environment, facilitates the implementation of ICH and other internationally harmonised technical guidelines for pharmaceuticals for human use, promotes collaboration and regulatory convergence, and contributes to the

coordination of a range of international efforts related to regulation of medicinal products for human use.

In July 2023, the ICH Assembly further approved the renewal of the MoU for an extended term of 2 years so that the ICH Secretariat would continue the provision of support services to the IPRP in 2024 and 2025.

5.6. External Cooperation

ICMRA PQ KMS Working Group

In 2023 ICH Representatives to the ICMRA (International Coalition of Medicines Regulatory Authorities) PQ KMS (Pharmaceutical Quality Knowledge Management System) supported the work towards the development of a Joint ICMRA-ICH-PICS-IPRP PQ KMS WG Work Plan detailing the work of each participating organisation, which was finalised in September 2023 and is available on the ICMRA website. Further work in 2023 included the organisation of a workshop on Development of a Pharmaceutical Quality Knowledge Management System in July 2023, with presentations and recording of the sessions available on the ICMRA website.

PIC/S

In October 2023 the ICH Assembly welcomed the signature of a MoU between ICH and PIC/S (Pharmaceutical Inspection Co-operation Scheme), with both parties engaged in pharmaceutical harmonisation activities, and PIC/S being an Observer in ICH since 2017 with many regulatory members in ICH also being "participating authorities" in PIC/S. This MoU is intended to facilitate collaboration on a number of ICH Guidelines that are relevant also for inspectorate activities and provide training for both assessors and inspectors.

As a part of the collaboration related to training activities, in 2023 ICH provided funding towards the development of PIC/S Inspectors Training on ICH Q9 and Q12 as a part of PIC/S Inspectorates' Academy (PIA), with training materials to be available for ICH Members and Observers via a dedicated platform in 2024.

5.7. ICH Secretariat

2023 Staffing

The following highlights key points and decisions related to ICH Secretariat staffing in 2023:

- ICH Secretariat staffing was initially planned at **12 FTEs (Full Time Equivalents) for 2023**, allocated between ICH (~ 8.5 FTEs) and MedDRA (~ 3 FTEs) activities, as well as IPRP support (~ 0.5 FTEs), with 2 new positions having been approved at the end of 2023. However, the ICH Secretariat operated at less than full capacity in 2023, during the year due to staff changes, staff leave, as well as delays in hiring support for both vacant and new positions.
- The year saw **Coordinator Ms. Lucie Archambeau, Assistant Ms. Charlotte Rémié, Coordinator Mr. David Demyttenaere** and **Coordinator Ms. Petra Grand,** join the

team in June, August and October respectively, with **Manager Ms. Olga Frei** and **Coordinator Ms. Clarisse Bertherat** leaving the ICH Secretariat during the year.

2023 ICH Secretariat Key Activities

The following outlines key activities undertaken by the ICH Secretariat in 2023 in accordance with its responsibilities for day-to-day ICH management, WGs support, and the support of the Assembly, the ICH Management Committee and the MedDRA Management Committee and the implementation of their respective decisions and directives.

2023 Day-to-Day Management Key Activities:

- **Preparing agenda papers and reports** for meetings of the Assembly, the ICH Management Committee and the MedDRA Management Committee. This included the biannual meetings of these governing bodies in June and October-November 2023.
- **Supporting ICH harmonisation activities** and the work of **33 ICH WGs** in 2023, including keeping up-to-date membership lists, and providing support for the use of MS SharePoint and MS Teams by WGs.
- **Providing support and input for the work of the following ICH Management Committee Subcommittees**: Finance; Training; and New Topics.
- **Drafting ICH Association Reports and Work Plans** in support of ICH Management Committee and MedDRA Management Committee reporting to the Assembly, including: 2022 Annual Report; 2024 ICH Work Plan and ICH Multi-Annual Strategic Plan; and 2024 MedDRA Work Plan. All documents were approved by the ICH Assembly.
- **Maintaining the ICH website** including:
  - **Keeping the ICH website up-to-date** with publication of draft documents for public consultation, final ICH Guidelines, *Step 2* and *Step 4* presentations, regional public consultation dates, guideline implementation status and dates, ICH Management Committee and Assembly Meeting Reports, ICH WG Training Materials, Press Releases, ICH Training Materials as well as ICH Award recipients.
  - Maintaining up-to-date the publication on the ICH website, as part of **ICH's communication strategy and transparency policy,** the photographs and short biographies of all ICH Assembly, ICH Management Committee and MedDRA Management Committee Representatives, Member Coordinators and ICH Secretariat, as well as the list of experts' names for all active WGs.
  - Overseeing, inputting into and reviewing the work of the website developer contracted to: maintain **the ICH, Private Platform, and MedDRA websites** along with the **internal database interfaced with the websites**.
  - **Managing the hosting of ICH websites**.
- **Responding to stakeholder enquiries** received via the ICH mailbox with input solicited as necessary from ICH experts and ICH Coordinators in accordance with the process for managing technical questions received.
- **Managing ICH's financial administration**, including: regular coordination with the fiduciary firm providing accountancy services to ICH; authorisation of payments; drafting of ICH and MedDRA budgets and multi-year budget plans; organising the

financial audit; liaising with the relevant Swiss tax authorities for items including submission of 2022 tax return and quarterly VAT declarations; managing ICH's grant agreement with FDA, United States, which in 2022 included submitting an annual Federal Financial Report; and supporting the oversight of assets under the direction of the ICH Finance Committee in line with the approved Asset Preservation Policy.

- Managing ICH general administration, including ensuring compliance with requirements for Swiss organisations, including responding to requests from the Swiss authorities for information;
- **Entering into and managing contracts**, including those related to day-to-day operations (e.g., office support, website hosting/maintenance, MS SharePoint, MS Teams, web conferencing tools etc.), specific projects (e.g., Training Associates, Implementation Survey), as well as support of the MedDRA Management Committee's oversight of the MSSO Contractor.
- **Controlling use of the ICH logo** (including ICH Member) in line with the agreed procedures governing its use.
- **Supporting the logistical organisation of ICH biannual meetings and ICH Management Committee interim meeting** including: regular coordination with and oversight of the PCO.
- **Supporting the ICH Assembly in the delivery of the ICH Award for Outstanding Contribution to ICH Harmonisation for Better Health.**

2023 New/One-Time/Key Activities:

- **Supporting ICH Guideline implementation activities** by engaging Centre for Innovation in Regulatory Science (CIRS), an independent third party contracted in 2023 to conduct the implementation survey, launched early January 2024.
- **Supporting an amendment of the agreement with the new PCO** for providing support with organising the interim meeting in March 2024 in Lisbon, Portugal.
- **Supporting the establishment of a MoU between ICH and PIC/S** to facilitate collaboration on a number of ICH Guidelines that are relevant for inspectorate activities and provide training for both assessors and inspectors.
- **Supporting launch of Request for Proposal** process in November 2023 to identify and contract a **Technical Writer** to support WG Guideline development.
- **Managing ICH's trademark registration strategy** for the **ICH logo (device)** which was approved by the ICH Management Committee, and for the **MedDRA logo (device) and name**, which was approved by the MedDRA Management Committee. In 2023, this effort included filing registrations in Tunisia (MedDRA & ICH trademarks) and Israel (ICH trademarks); signing of Power of Attorney as needed; and general provision of input to the trademark lawyers for: class descriptions; responding to trademark authority questions and refusals; and considering other new applications for trademarks similar to ICH and MedDRA trademarks, and follow-up with ICH and MedDRA Management Committee Chairs on key decision items.
- **Supporting the MedDRA Management Committee** with activities including:
    - Follow-up on **contract-related matters**, including seeking the necessary legal input;

- Supporting **engagement of auditor** for MSSO Financial Audit;
- Support related to assessing MedDRA business continuity, particularly in the face of recent global events, and considering response to potential interruptions, and in various scenarios, to ensure the current high level of functionality which MedDRA users have come to expect.

- **Identifying opportunities for enhanced efficiencies** in the ICH Secretariat's management of the day-to-day operations of the ICH Association to ensure a mindful and well-appropriated use of ICH Secretariat resources.
- **Supporting the engagement of 4 external organisations in support of the activities and development of permitted daily exposures (PDE) reports** for the development of the Q3E Guideline.
- **Identifying a new larger office space for the ICH Secretariat** and initiating planning with a view to moving office in early 2024.

5.8. ICH & MedDRA Management Committee Appointed Signatories

At the end of 2023, ICH signatories in line with Article 36 2(e) and 47 2(e) of the ICH Articles of Association, to represent the ICH Association vis-à-vis third parties are: ICH Assembly Chair Ms. Lenita Lindström, Assembly Vice Chair Dr. Gabriela Zenhäusern, ICH Secretariat staff Ms. Emilie Macara and Dr. Dawn Ronan, with Ms. Luludi being approved by the ICH Management Committee in June 2023 as a new ICH signatory in support of ICH operations. All signatories have joint (by two) signatory rights.

Annex I

Assembly Member Representatives & Observer Delegates

December 31, 2023

Founding Regulatory Members

EC, Europe
Dr. Georgios Balkamos
Ms. Lenita Lindström *(Chair)*
Dr. Bruno Sepodes

FDA, United States
Dr. Theresa Mullin
Dr. Michelle Limoli

MHLW/PMDA, Japan
Mr. Daisuke Koga
Mr. Naoyuki Yasuda

Founding Industry Members

EFPIA
Mr. Raun Kupiec
Mr. Pär Tellner

JPMA
Dr. Manabu Yanagisawa
Dr. Masafumi Yokota

PhRMA
Dr. Michelle Rohrer
Ms. Janet Vessotskie

Standing Regulatory Members

Health Canada, Canada
Dr. Léo Bouthillier
Mr. Bruce Randall

Swissmedic, Switzerland
Dr. Andreas Pfenninger
Dr. Gabriela Zenhaeusern *(Vice-Chair)*

Regulatory Members

ANVISA, Brazil
Mr. Nélio Cezar de Aquina
Ms. Bianca Zimon

COFEPRIS, Mexico
Ms. Miriam Jackeline Loera Rosales
Dr. Alejandro Ernesto Svarch Pérez

EDA, Egypt
Ms. Asmaa Fouad

HSA, Singapore
Ms. Siew Wei Chua
Dr. Dorothy Toh

MFDS, Republic of Korea
Dr. Seogyoun Kang
Dr. Younglim Kim

MHRA, UK
Ms. Gavia Taan
Dr. Glenn Wells

NMPA, China
Dr. Sheng Yang
Mr. Siyuan Zhou

SFDA, Saudi Arabia
Dr. Adel Alharf
Dr. Abdullah Hamad Al Hatareshah

TFDA, Chinese Taipei
Dr. Jo-Feng Chi
Ms. Mei-Chen Huang

TITCK, Turkey
Dr. Elif İnci Ergönül
Ms. Handan Öztunca

Industry Members

BIO
Dr. Wassim Nashabeh
Ms. Nancy Schwalje Travis

Global Self-Care Federation
Dr. Padmaja Kamath
Ms. Judy Stenmark

IGBA
Dr. Nick Cappuccino
Ms. Beata Stepniewska

Standing Observers

IFPMA
Ms. Angelika Joos
Ms. Judith MacDonald

WHO
Dr. Samvel Azatyan
Mr. Hiiti B. Sillo

Observers

AEC, Azerbaijan
Mr. Farid Hasanov

ANMAT, Argentina
Ms. Yanina Rodriguez

ANPP, Algeria
Dr. Amel Bensedira

APEC
Ms. Younjoo Park

APIC
Dr. Rainer Fendt

ASEAN
Ms. Worasuda Yoongthong

Bill and Melinda Gates Foundation
Dr. Murray Lumpkin

CDSCO, India
Dr. Rajeev Singh Raghuvanshi

CECMED, Cuba
Dr. Celeste Sánchez González

CIOMS
Dr. Lembit Rägo

CPED, Israel
Dr. Ofra Axelrod

DPM, Tunisia
Prof. Abderrazek Hedhili

EAC
Mr. Felchism Apolnary Oisso

EDQM
Dr. Petra Doerr

GHC
Dr. Hajed M. Hashan

Indonesian FDA, Indonesia
Ms. Mimin Jiwo Winanti

INVIMA, Colombia
Ms. Yenny Marcela Suárez González

IPEC
Ms. Janeen Skutnik-Wilkinson

JFDA, Jordan
Dr. Wesal Haqaish

MMDA, Moldova
Mr. Dumitru Saghin

MOPH, Lebanon
Dr. Colette Raidy

NAFDAC, Nigeria
Prof. Christianah Mojisola Adeyeye

National Center, Kazakhstan
Prof. Shynar Baidullayeva

NPRA, Malaysia
Ms. Rosilawati Ahmad

NRA, Iran
Dr. Mahmoud Alebouyeh

PANDRH
Ms. Maria Luz Pombo-Castro

PIC/S
Mr. Daniel Brunner

PPBHK, Hong Kong, China
Mr. Frank Chan Ling-Fung

Roszdravnadzor, Russia
Ms. Anastasia Nikitina

SADC
Ms. Fortunate Ntombi Bhembe

SAHPRA, South Africa
Ms. Portia Nkambule

SCDMTE, Armenia
TBC

SECMOH, Ukraine
Dr. Mykhailo Babenko

TGA, Australia
Mr. Michael Wiseman

USP
Dr. Kevin Moore

Annex II

ICH Management Committee Representatives

December 31, 2023

Founding Regulatory Members

EC, Europe
Dr. Milton Bonelli
Ms. Lenita Lindström

FDA, United States
Dr. Theresa Mullin *(Chair)*
Dr. Michelle Limoli

MHLW/PMDA, Japan
Mr. Daisuke Koga
Dr. Shinichi Okudaira
Mr. Naoyuki Yasuda (*Vice-Chair*)

Founding Industry Members

EFPIA
Mr. Raun Kupiec
Mr. Pär Tellner

JPMA
Dr. Manabu Yanagisawa
Dr. Masafumi Yokota

PhRMA
Dr. Michelle Rohrer
Ms. Janet Vessotskie

Standing Regulatory Members

Swissmedic, Switzerland
Dr. Andreas Pfenninger
Dr. Gabriela Zenhaeusern

Health Canada, Canada
Dr. Léo Bouthillier
Mr. Bruce Randall

Standing Observers

WHO
Dr. Samvel Azatyan
Mr. Hiiti B. Sillo

IFPMA
Ms. Angelika Joos
Ms. Judith MacDonald

Regulatory Members

ANVISA, Brazil
Mr. Nélio Cezar de Aquina
Ms. Bianca Zimon

MFDS, Republic of Korea
Dr. Seogyoun Kang
Dr. Younglim Kim

NMPA, China
Dr. Sheng Yang
Mr. Siyuan Zhou

Industry Members

BIO
Dr. Wassim Nashabeh
Ms. Nancy Schwalje Travis

IGBA
Dr. Nick Cappuccino
Ms. Beata Stepniewska

Annex III

MedDRA Management Committee Representatives

31 December, 2023

Founding Regulatory Members

EC, Europe
Dr. Georgios Balkamos
Dr. Ana Cochino

FDA, United States
Ms. Mary Ann Slack
Dr. Barbee I. Whitaker (*Chair*)

MHLW/PMDA, Japan
Mr. Masahiro Inada
Mr. Takayuki Okubo

Founding Industry Members

EFPIA
Ms. Claudia Lehmann
Dr. Christina Winter

JPMA
Ms. Mamiko Kasho (Konishi)
Ms. Yasuyo Suzuki

PhRMA
Dr. Maria Apostolaros
Mr. Kostas Kidos

Standing Regulatory Member

Health Canada, Canada
Dr. Craig Simon (*Vice-Chair*)

Regulatory Members

MHRA, UK
Mr. Mick Foy
Mr. Philip Tregunno

Standing Observers

WHO
Mr. Fumihito Takanashi

Annex IV

ICH Secretariat Staff

31 December, 2023

Director
Dr. Dawn Ronan

Managers
Mr. Sivashen Cunden
Ms. Nikoleta Luludi
Ms. Emilie Macara

Coordinators
Ms. Lucie Archambeau
Mr. David Demyttenaere
Ms. Petra Grand
Ms. Anca-Elena Matei

Administrative Assistants
Ms. Amina Mir
Ms. Charlotte Rémié

Annex V

Assembly Member and Standing Observer ICH Coordinators

31 December, 2023

Founding Regulatory Members

EC, Europe
Dr. Georgios Balkamos
Dr. Kevin Cunningham (Technical Coordinator)

MHLW/PMDA, Japan
Ms. Mao Matsumoto
Dr. Takashi Misu (Technical Coordinator)

FDA, United States
Ms. Jill Adleberg
Dr. Michelle Limoli (Technical Coordinator)

Founding Industry Members

EFPIA
Dr. Jyothsna Krishnan

JPMA
Ms. Mariko Kato

PhRMA
Ms. Amanda Roache

Standing Regulatory Members

Swissmedic, Switzerland
Ms. Sarah Koechlin

Health Canada, Canada
Mr. Nick Orphanos

Regulatory Members

ANVISA, Brazil
Ms. Ana Carolina Moreira Marino Araujo

COFEPRIS, Mexico
Ms. Margarita Contreras Olvera

EDA, Egypt
Dr. Sondos Moshtohry

HSA, Singapore
Ms. Shu Yi Ong

MHRA, UK
Mr. Gordon Wood

MFDS, Republic of Korea
Dr. Hyun Song

NMPA, China
Mr. Baoshu Wen

SFDA, Saudi Arabia
Mr. Yahya Al-Nujaym

TFDA, Chinese Taipei
Ms. Yi-Ju Lin

TITCK, Turkey
Dr. Elif İnci Ergönül

Industry Members

BIO
Ms. Casey Rosner

IGBA
Dr. Shinichiro Hirose

Global Self-Care Federation
Dr. Padmaja Kamath

Standing Observers

IFPMA
Ms. Lidija Samardzic

WHO
Ms. Marion Laumonier

Annex VI

Overview of harmonisation activities and accomplishments in 2023

Topic Code	Type of WG	Topic Name	Accomplishments	Anticipated Milestones
Standing Paediatric	EWG	Standing Paediatric		N/A (Ongoing Activity)
E2B(R3)	EWG/IWG	Revision of Electronic Submission of ICSRs	*Steps 4* for the ICH E2B(R3) Q&As Version 2.4 were reached in January 2023.	Training Module III is expected by March 2024
E2D(R1)	EWG	Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting		*Step 2* is expected by February 2024
E6(R3)	EWG	Good Clinical Practice	*Step 2* was reached in May 2023 (Principles & Annex 1)	*Step 4* is expected by October 2024 (Principles & Annex 1) *Step 2* expected by August 2024 (Annex 2)
E11A	EWG	Paediatric Extrapolation		*Step 4* is expected by Q2 2024
E14/S7B	DG	Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential	Previously an EWG, transitioned to a DG starting in January 2023 for a one-year term to evaluate implementation of first stage Q&As and outline development of second stage Q&As	Concept Paper for second stage Q&As is expected in Q1 2024

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E20	EWG	Adaptive Clinical Trials		*Step 2* is expected by November 2024
E21	EWG	Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials		*Step 2* is expected by Q1/Q2 2025
M1	PtC WG	MedDRA Points to Consider	Release of updated "MedDRA Term Selection" and "MedDRA Data Retrieval and Presentation" PtC documents released in March 2023 (based on MedDRA Version 26.0)	Release of updated "MedDRA Term Selection" and "MedDRA Data Retrieval and Presentation" PtC documents expected in March 2024 (based on MedDRA Version 27.0)
M2	EWG	Electronic Standards for the Transfer of Regulatory Information (ESTRI)		N/A (Ongoing Activity)
M4Q(R2)	EWG	General principles on planning and designing pharmacoepidemiological studies that utilize real-world data for safety assessment of a medicine		*Step 2* is expected by November 2024

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M7(R3)	Maintenance EWG/IWG	Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk	*Step 4* was reached for the M7(R2) revised Guideline and Addendum in April 2023	N/A (Ongoing Activity)
M8	M2 Sub-group	The Electronic Common Technical Document (eCTD)		*Step 4* is expected in Q1 2024 for the ICH M8 eCTD "v3.0 Q&As and Specification Change Request Document v1.3.3" and eCTD "v4.0 Q&As and Specification Change Request Document v1.8"
M10	EWG	Bioanalytical Method Validation and Study Sample Analysis		Training Materials are expected by February 2024
M11	EWG	Clinical electronic Structured Harmonised Protocol (CeSHarP)		*Step 4* is expected by November 2025 (Guideline, Template and Technical Specification) and Technical Implementation Guide by May 2026

Topic Code	Type of WG	Topic Name	Accomplishments	Anticipated Milestones
M12	EWG	Drug Interaction Studies		*Step 4* is expected by Q1 2024
M13	EWG	Bioequivalence for Immediate-Release Solid Oral Dosage Forms		*Step 4* is expected by July 2024 (M13A), by December 2024 (M13B)
M14	EWG	General principles on plan, design, and analysis of pharmacoepidemiological studies that utilize real-world data for safety assessment of medicine		*Step 2 is* expected by August 2023
M15	EWG	General Principles for Model-Informed Drug Development		*Step 2* is expected in September 2024
Q1/Q5C	EWG	Targeted Revisions of the ICH Stability Guidelines Series		*Step 2* is expected by December 2024
Q2(R2)/ Q14	EWG	Analytical Procedure Development and Revision of Q2(R1) Analytical Validation	*Step 4* was reached in November 2023, further to which the EWG transitioned to an IWG	Training Materials are expected by November 2024
Q3C(R9)	Maintenance EWG	Residual Solvents		N/A (Dormant state)
Q3D(R3)	Maintenance EWG	Maintenance of the Guideline for Elemental Impurities		N/A (Dormant state)

Topic Code	Type of WG	Topic Name	Accomplishments	Anticipated Milestones
Q3E	EWG	Impurities: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics		*Step 2* is expected by June 2025
Q5A(R2)	EWG	Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin	*Step 4* was reached in November 2023, further to which the EWG transitioned to an IWG	Training materials are expected by October 2024
Q9(R1)	IWG	Quality Risk Management	*Step 4* was reached in January 2023	Training Materials are expected by June 2024
Q12	IWG	Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management		Training Material Module 8 is expected shortly
Q13	IWG	Continuous Manufacturing of Drug Substances and Drug Products		Training materials are expected by June 2024
S1B(R1)	EWG	Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline		Establishment of the IWG expected shortly

Topic Code	Type of WG	Topic Name	Accomplishments	Anticipated Milestones
S5(R4)	Maintenance EWG	Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals		N/A (Dormant State)
CGTDG	DG	Cell and Gene Therapies Discussion Group		Recommendation paper expected by October 2025
GDG	DG	Generic drug Discussion Group		N/A (Dormant state)
QDG	DG	Quality Discussion Group		N/A (Ongoing activity)