



# ICH Association

## 2024 Annual Report

**ICH Association**  
**2024 Annual Report**

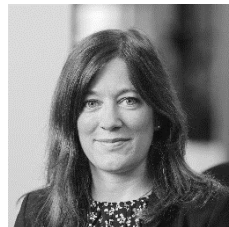
*Prepared by the ICH Secretariat with the ICH Management Committee and MedDRA  
Steering Committee approval of their respective sections*

*Version dated 28 April 2025*

*Approved by the ICH Assembly on 13 May 2025*



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## **Message from Assembly Chair and Vice Chair**

*The ICH Association is proud to reflect on its collective achievements over the past year.*

*In 2024, significant progress was made in harmonisation efforts, highlighted by the finalisation and publication of three new Guidelines: E11A Guideline on “Pediatric Extrapolation”, M12 Guideline on “Drug Interaction Studies”, and M13A Guideline on “Bioequivalence for Immediate-Release Solid Oral Dosage Forms”; and the revision and release of two existing Guidelines: Q3C(R9) and Q4B(R1). Particularly, the finalisation of ICH E11A Guideline is crucial for advancing paediatric drug development and authorisation by providing recommendations and promoting international harmonisation of paediatric extrapolation.*

*In line with ICH procedures, elections were held for Elected Representatives to the ICH Management Committee, welcoming for a 3-year term Representatives from Regulatory Members: ANVISA, Brazil; MFDS, Republic of Korea; NMPA, China; and SFDA, Saudi Arabia and Industry Members: BIO and IGBA. In support of these elections, a survey was conducted to evaluate the implementation and adherence to ICH Guidelines across Regulatory Member and Observer countries/regions. The results of the survey reveal strong progress in the adoption of ICH Guidelines, building on the momentum established by the 2019 and 2021 surveys.*

*The continued expansion of ICH membership highlights a steadfast commitment to global harmonisation. This year, CPPS, Uzbekistan; DIGEMID, Peru and Thai FDA, Thailand were welcomed as Observer Regulatory Authorities, while ANMAT, Argentina and JFDA, Jordan joined as new Regulatory Members.*

*As Chair and Vice-Chair of the Assembly, heartfelt gratitude is expressed to all colleagues and stakeholders for their ongoing dedication and support. The ICH Association eagerly anticipates the continued progress and impactful work that lies ahead.*

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## 1. About ICH

### 1.1. Purpose & Aims

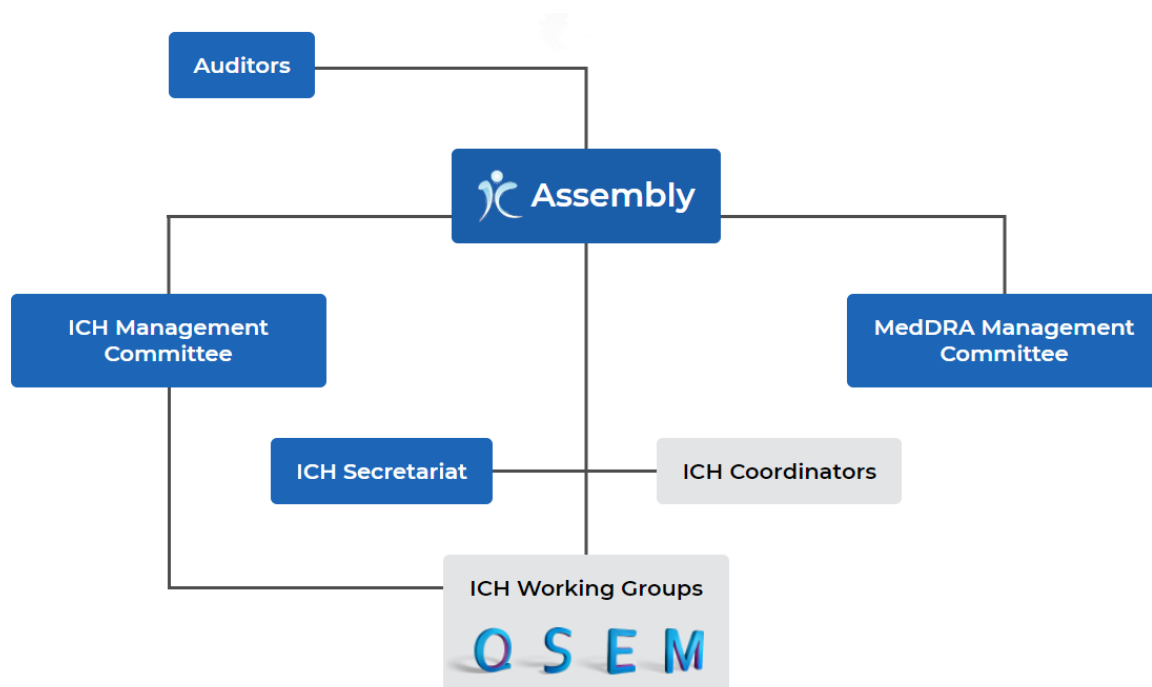
The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is an **international non-profit organisation** which was established as an association under Swiss law in October 2015. The purpose of ICH is to **promote public health through international 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, 2024 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 2024 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, 2024 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, 2024 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 2024 are referred to in Section 5.7.
- ✧ The full list of ICH Secretariat Staff as of December 31, 2024 is provided in Annex IV.

### Auditors

- ✧ In 2024, 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 2024 and 2025.

### 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, 2024 is provided in Annex V.

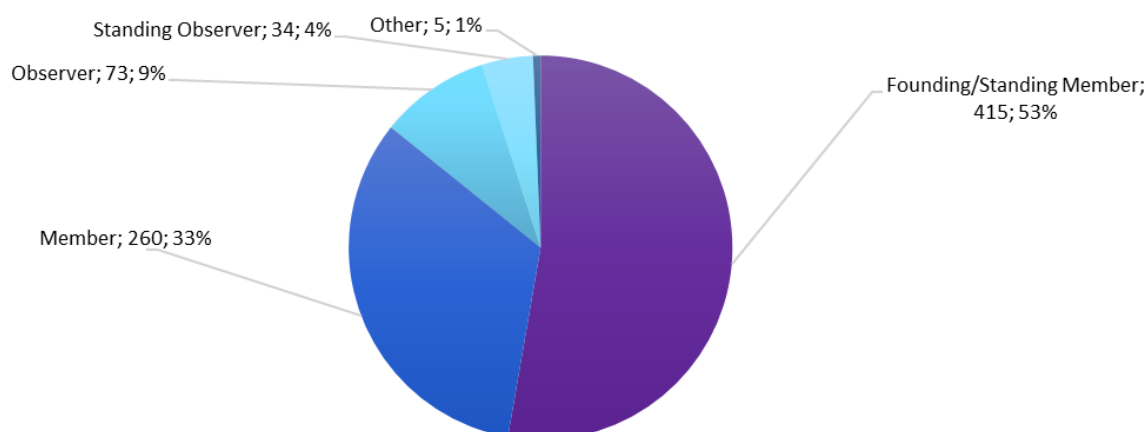
## 2. 2024 Overview of ICH Membership & Observership

### *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 2024 saw the addition of 2 new Members and 3 new Observers, bringing ICH to a total of **23 Members and 38 Observers**. By the end of 2024 over 1,250 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 2024 these WGs involved the participation of **over 780 technical experts**.

## Number of experts in ICH WGs



### Overview of Expert Participation in ICH, as of October 2024

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 2024 PWPs had been established for 8 WGs (ICH E2D(R1), E6(R3), E20, E22, M4Q(R2), M15, Q1, 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 2024**

At the meeting in Fukuoka, Japan in June 2024, the Assembly approved ANMAT, Argentina and JFDA, Jordan as **new ICH Regulatory Members**, while at the meeting in Montreal, Canada in November 2024, the Assembly welcomed CPPS, Uzbekistan; DIGEMID, Peru and Thai FDA, Thailand as **new ICH Regulatory Observers**.

## **3. 2024 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 2024, these activities were progressed on **36 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 2024** relating to ICH harmonisation efforts include the following documents, available on the [ICH website](https://ich.org):

- ✧ Completion at **Step 4** of the ICH process and **finalisation** of work (please see Section 3.1) on:
  - ✧ **3 New Guidelines**: E11A, M12, M13A;
  - ✧ **2 Revised Guidelines**: Q3C(R9), Q4B(R1)
  - ✧ **2 New Q&As**: M12 Q&A, M13A Q&A;
  - ✧ **1 Revised Q&As**: Q8/Q9/Q10 Questions & Answers (R5);
  - ✧ **1 Updated Implementation Guide package**: M8 Work Products;
- ✧ Reaching of **Step 2a/b** of the ICH process and completion of drafts (please see Section 3.2) of:
  - ✧ **3 New Guidelines** – E6(R3) Annex 2, M14, M15;
  - ✧ **1 Revised Guideline** – E2D(R1);
- ✧ **1 New Topic** was approved in 2024 (see Section 3.3) – M7 Sub-Group.

An overview of all ICH WG activities and accomplishments in 2024 is presented in Annex VI.

### ***3.1. ICH Guidelines & Other WG Work Products Finalised in 2024***

Please note that all ICH documents referenced below can be found on the ICH website at [ich.org](https://ich.org).

#### **ICH E11A Guideline - Paediatric Extrapolation**

*Steps 3 and 4* for the ICH E11A Guideline were reached in August 2024.

This new Guideline provides a framework for extrapolation to support paediatric drug development. The framework describes an iterative process for understanding the existing information available, the gaps in information needed to inform development, and ways to generate additional information when required and recommends approaches to assessing factors that influence the determination of similarity of disease, drug pharmacology, and response to treatment between a reference and paediatric target population.

#### **ICH M12 Guideline and M12 Q&As - Drug Interaction Studies**

*Steps 3 and 4* for the ICH M12 Guideline and Q&As were reached in May 2024.

This new Guideline and associated Q&As provide recommendations to promote a consistent approach in designing, conducting, and interpreting enzyme- or transporter-mediated in vitro and clinical drug-drug interaction (DDI) studies during the development of a therapeutic product. The supporting Q&As are intended to provide additional clarification and improve harmonization of drug interaction assessment.

#### **ICH M13A Guideline and M13A Q&As - Bioequivalence for Immediate-Release Solid Oral Dosage Forms**

*Steps 3 and 4* for the ICH M13A Guideline and M13A Q&As were reached in July 2024.

This new Guideline and associated Q&As provide recommendations on conducting bioequivalence studies during both the development and post-approval phases for orally administered immediate-release solid oral dosage forms. The Q&A document is intended to provide additional clarification and improve harmonisation of bioequivalence study design and data analysis.

### **ICH Q3C(R9) Guideline – Impurities: Guideline for Residual Solvents**

*Steps 3 and 4* for the ICH Q3C(R9) Guideline were reached in January 2024.

The revised Guideline includes minor revisions to section 3.4 of the Guideline for considerations towards solvent volatility for analytical methods.

### **ICH Q4B(R1) Guideline – Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions**

*Steps 4* for the ICH Q4B(R1) Guideline were reached in June 2024.

The PDG revised this Guideline following the endorsement of the maintenance procedure to reflect that responsibility for the maintenance of Q4B and its annexes was handed over to the PDG. Process and individual interchangeability statements taken out and transferred to the ICH SOP or specific Q4B annexes.

### **ICH Q8/Q9/Q10 Q&As (R5) – Training Programme for Implementation of ICH Q8/Q9/Q10**

*Steps 3 and 4* for the ICH Q8/Q9/Q10 Q&As (R5) were reached in November 2024.

The revised Q&As were updated to remove outdated text and rephrasing the Q&As considered in view of the implementation of ICH Q8, Q9 and Q10, with minor additions to address minor content gaps in the document.

### **ICH M8 Implementation Guide package – Electronic Common Technical Document (eCTD)**

*Steps 3 and 4* for the ICH M8 Implementation Guide package were reached in May 2024.

The M8 Implementation Guide package contains revised eCTD v.3.2.2 Q&A, eCTD V3.2.2 Valid Values v6.0, eCTD v4.0 Q&A v1.8, eCTD v4.0 Implementation Guide v1.6 and new eCTD v4.0 Controlled Vocabulary Package v1.0 to aid implementation of the ICH M8 Guideline.

## ***3.2. ICH Guidelines Endorsed at Step 2a/b in 2024***

In 2024 the following ICH Guidelines 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 E2D(R1) Guideline - Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports**

*Steps 1 and 2a/b* were reached for the revised draft Guideline in February 2024.

The revised draft Guideline provides guidance on definitions and standards for post-approval individual case safety reporting, as well as good case management practices. This guideline was originally based on the content of the ICH E2A guideline (which provides guidance on pre-approval safety data management), with consideration as to how the terms and definitions should be applied in the post-approval phase of the product life cycle.

### **ICH E6(R3) Guideline - Good Clinical Practice (GCP) Annex 2**

*Steps 1 and 2a/b* were reached for the new draft Guideline in November 2024.

The new draft Guideline addresses the application of GCP principles to the increasingly diverse trial types and data sources being employed to support regulatory and healthcare related decision-making on drugs, and provide flexibility whenever appropriate to facilitate the use of technological innovations in clinical trials.

### **ICH M14 Guideline - General principles on plan, design, and analysis of pharmacoepidemiological studies that utilize real-world data for safety assessment of medicine**

*Steps 1 and 2a/b* were reached for the new draft Guideline in May 2024.

The new draft Guideline provides recommendations and high-level best practices for the conduct of non-interventional studies to streamline the development and regulatory assessment of study protocols and reports.

### **ICH M15 Guideline - General Principles for Model-Informed Drug Development**

*Steps 1 and 2a/b* were reached for the revised draft Guideline in November 2024.

The new draft Guideline provides general principles and good practices for the use of Model-Informed Drug Development (MIDD) and harmonises expectations regarding documentation standards, model development, data used in the analysis, model assessment, and its applications.

## **3.3. New Harmonisation Activities**

### **3.3.1. Approval of New Topics**

In view of an important backlog of approved topics to start, in 2024 only topics considered as urgent by ICH Management Committee and of potential high public health interest were recommended for further Assembly consideration.

Further to this, assessments for 2 **proposals** were prepared for the Assembly, and the ICH Management Committee provided its recommendation for **1 New Topic proposal**.

Based on the ICH Management Committee assessment, the Assembly approved the following 1 new harmonisation activity:

#### **Addendum to ICH M7 on Risk Assessment and Control of Nitrosamine Impurities**

This new ICH Addendum to the M7 Guideline on Assessment and Control of DNA Reactive (mutagenic) Impurities will address safety assessment and establishment of appropriate controls for nitrosamine impurities. This Addendum will focus on developing general principles and approaches for determining acceptable intakes (AIs) and a general approach to minimize the presence of nitrosamine impurities. Towards this addendum, it is also proposed to develop a harmonized set of acceptable intakes and training materials, including examples, to elaborate on relevant quality principles and the application of M7 to nitrosamines risk assessment and control.

✧ The M7 Sub-Group was established in August 2024.

#### **3.3.2. Other New Harmonisation Activities**

In 2024, work on other new harmonisation activities included the finalisation of Concept Papers for the following topics:

- ✧ ICH E14/S7B **Second Round Questions & Answers “Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential”**;
- ✧ ICH E22 EWG **“General Considerations for Patient Preference Studies”**;
- ✧ ICH Q3C(R10) **“Maintenance of the Guideline for Residual Solvents”**;
- ✧ ICH Q6(R1) **“Revision of the Specifications Guidelines”**;
- ✧ ICH S1B(R1) **“Training on Testing for Carcinogenicity of Pharmaceuticals”**;
- ✧ ICH S13 **“Nonclinical Safety Studies for Oligonucleotide-based Therapeutics”**.

In addition, the ICH M2 Electronic Standards for the Transfer of Regulatory Information (ESTRI) JavaScript Object Notation (JSON) recommendation was finalised by the M2 EWG and endorsed by the Assembly in May 2024.

#### **3.3.3. Strategic Reflection Papers**

In June 2024 the ICH Assembly endorsed an updated version of the ICH Reflection Paper on *“Pursuing Opportunities for Harmonization in Using Real-World Data to Generate Real-World Evidence, with a focus on Effectiveness of Medicines”* which was published on the ICH website.

### **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 “**Tier2**” 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](https://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 launched for the third time in January 2024 in coordination with the Centre for Innovation in Regulatory Science (CIRS), an independent third party contracted by ICH to conduct the survey. The objective of the study was 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 were presented at the ICH meeting in Fukuoka in June 2024, and subsequently a report was developed by CIRS and published on the ICH website in October 2024.

The results demonstrate a strong level of implementation and adherence to the ICH Guidelines with a good alignment between the perception of the pharmaceutical companies and the self-declaration from the assessed authorities. This shows authorities’ and companies’ continued commitment and support in ICH’s mission to achieve greater harmonisation worldwide and ensure that safe, effective, and high-quality medicines are developed, registered, and maintained in the most resource-efficient manner whilst meeting high standards.

### ***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 2024 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; and the development of training materials by **ICH Working Groups**.

In addition, in 2024 the work was progressed on the following key areas for improvement of ICH training processes / activities progressed by 3 Training Sub-groups established 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 2024 in particular on the following deliverables:

- Development of an ICH Training Subcommittee slide deck to be used internally for new Training Subcommittee members; and establishment of categories for the existing ICH training materials, with ongoing work on a holistic map of ICH Guidelines including direct links to Guideline pages, and an ICH infographic;
- Analysis of results of a Survey on ICH Training Needs launched between July - September 2023 among all ICH Regulatory Members and Observers, as well as Industry Trade Associations, with recommendations for future considerations to focus on prospective Training Associates activities to fund advanced trainings, and to leverage existing trainings (e.g., past ICH-funded Regulatory Trainings).

2024 saw a sunset of the ICH Training Subcommittee, including its 3 Training Sub-groups, with ICH Training Co-Leads and ICH Finance Committee Chairs to oversee core and prioritised training activities with support from the MC Coordinators and ICH Secretariat.

#### 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 4 Training Associates

between 2020-2022, 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, E8(R1) Efficacy Guidelines introductory overview video developed by one Training Associate was published on the ICH website in October 2024.

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.**

#### ICH Regulatory Training

2024 also saw the ICH Management Committee approve the **provision of ICH funding support to training programmes on ICH Guidelines organised by 7 ICH Regulatory Members and 3 ICH Regulatory Observer.** This came further to a Call for Expression of Interest launched by the ICH Management Committee in December 2023 and saw support provided for training planned in 2024 by:

- ✧ ANPP, Algeria: Structure and content of clinical study report
- ✧ EAC: ICH Q5A-Q5E Quality of Biotechnological Products
- ✧ EDA, Egypt: Pharmaceutical Development and Analytical Procedures Development for regulators / for Industry and Junior regulators
- ✧ HSA, Singapore: ICH Q12 Training course
- ✧ NAFDAC, Nigeria: Drug Stability and Good Manufacturing Practice
- ✧ NMPA, China: Training on ICH Q2(R2) and Q14 Guidelines
- ✧ SFDA, Saudi Arabia: Efficacy considerations for human medicines

In addition, the following trainings were approved in 2024, and postponed to 2025 due to various reasons:

- ✧ ANVISA, Brazil: Pharmaceutical Continuous Manufacturing training
- ✧ Health Canada, Canada: Health Canada ICH E6(R3)
- ✧ JFDA, Jordan: Training on Technical and Regulatory Considerations for Pharmaceutical Product Life Cycle management / ICH Quality Guidelines

The Management Committee has also supported the following training approved in 2023, to be postponed to 2024, with the carry-over in the 2024 ICH budget to support this postponed training approved by the ICH Assembly:

- ✧ EDA, Egypt: Training on ICH Q8-Q12, E2C(R2), E2E, E8(R1)

In addition, progress was made in 2024 in particular on the following activities regarding the Regulatory Training process:

- Transition of the Call for Expressions of Interest to a rolling basis starting from 2025, with the call launched in December 2024, where submitted applications are verified for eligibility and shared with the ICH Management Committee (MC) for decisions at three key intervals each year: the MC Interim Meeting, the First Biannual Meeting, and the Second Biannual Meeting.
- Development of an ICH Funding of ICH Regulator Training on ICH Guidelines Frequently Asked Questions (FAQ) document which serves as a supporting resource to address any questions and is intended to be a living document, updated on an as-needed basis;
- Development of a new evaluation review process for Regulatory Trainings funded by ICH, for Regulators participating on a voluntary basis, which summarises the assessments of all completed Regulatory Training from 2024.

### 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 2024 work was finalised on developing training materials on the following ICH topics:

- ✧ E8(R1);
- ✧ M10;
- ✧ Q13.

### 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 2024, the following presentations were made available:

- ✧ ICH E2D(R1) *Step 2* Presentation;
- ✧ ICH E6(R3) Annex 2 *Step 2* Presentation;
- ✧ ICH M14 *Step 2* Presentation;
- ✧ ICH M15 *Step 2* Presentation;
- ✧ ICH E11A *Step 4* Presentation;
- ✧ ICH M12 *Step 4* Presentation;
- ✧ ICH M13A *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.



In 2024, MedDRA has been used by over 8900 organisations in 141 countries: the number of subscribing organizations worldwide is a clear indicator of the successful adoption of MedDRA over the past 25 years as a worldwide standard in the protection of public health. With the goal of ensuring MedDRA's continued responsiveness to the needs of global MedDRA users, MedDRA is currently available in 24 languages, with the recent release of Icelandic, Croatian and Lithuanian.

Continued MedDRA training and helpdesk support in 2024 by the MSSO (Maintenance and Support Services Organisation) was assisted by local support staff in Latin America, China, Europe, Russia, Middle East/Africa, India, Republic of Korea and United States.

#### 3.6.1. Overview of 2024 MedDRA Management & Key Decisions

The MedDRA Management Committee is responsible for overseeing the main activities of the MSSO, 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 2024 related to MedDRA's management:

##### ***Financial:***

- ✧ The MedDRA Management Committee supported the **2025 MedDRA Budget** including the stable **2025 MSSO Subscription Fees** (unchanged from 2024), subsequently approved by the Assembly.
- ✧ The MedDRA Management Committee approved the **2025 MSSO Business Plan**.

##### ***Operational:***

- ✧ The MedDRA Management Committee supported the **2025 Annual MedDRA Management Committee Work Plan** for submission to the Assembly, which was subsequently approved by the Assembly.
- ✧ The MedDRA MC oversaw the conduct of and approved the reports from a **MSSO Financial Audit** of the years 2021, 2022 and 2023, along with MSSO's response to findings. There were no major findings.
- ✧ 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 2024, this included the

renewal and declaration of use in the Maldives and Mexico, 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: Icelandic, Croatian and Lithuanian. The Procedure for Assessing New MedDRA Translations as well as the Request Form for a New MedDRA Translation, previously approved by ICH bodies, have been revised to update out-of-date information, including the number of translations.
- ✧ The MedDRA Management Committee supported the revision of the ICH/IMDRF Memorandum of Understanding (MoU), **expanding the scope of the IMDRF-MedDRA mapping** by removing the specific references to Annex E with the view that IMDRF and ICH would determine, on a case-by-case basis, which annexes will be mapped and maintained under the MoU, which was subsequently approved by the Assembly.
- ✧ The MedDRA Management Committee appointed Dr. Barbee Whitaker, FDA United States, to serve as **Finance Committee Co-Chair** for a two-year term and elected Dr. Craig Simon, Health Canada, to serve as the **MedDRA MC Vice-Chair** for a two-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 the addition of the ICH Secretariat staff, Ms. Nikoleta Luludi and Ms. Lucie Archambeau as **new MedDRA signatories** in line with Article 47 2(e) of the ICH Articles of Association to represent the ICH Association vis-à-vis third parties on matters relating to MedDRA alongside existing ICH signatories with joint (by two) signatory rights.

#### ***Development of SMQs:***

- ✧ SMQs are tools developed to facilitate retrieval of MedDRA-coded data as a first step in investigating drug safety issues in pharmacovigilance and clinical development. **Currently, 110 SMQs are in production.** No new SMQs went into production in MedDRA v27.1. The Neurodevelopmental disorders EWG decided not to pursue further development of the Neurodevelopmental disorders SMQ.

#### **3.6.2. Oversight of 2024 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 2024, which were overseen by the MedDRA Management Committee:

- ✧ Release to users of MedDRA versions 27.0 and 27.1 on 1 March and 1 September 2024 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. The

launch of the MedDRA Learning Management System (LMS) that is free to all MedDRA users is planned at the beginning of 2025.

- ✧ 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; Norwegian MedDRA translations initiated in 2022; Slovenian initiated in 2023; Bulgarian, Slovakian and Danish initiated in 2024; Croatian, Lithuanian and Icelandic were released in 2024.
- ✧ Maintenance and development of **software tools for** MedDRA users e.g., Web-based Browser, Desktop Browser, Version Analysis tool etc. In 2024, work continued on the exploration of the use of Artificial Intelligence (AI) / Machine Learning (ML) for use within the MedDRA MSSO and/or create new products for MedDRA users.
- ✧ Support for **mapping with other terminologies** in 2024: (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 2024; (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 April 2024; and (3) continued cooperation with WHO on the **MedDRA-ICD 10/11 mappings**: the maintenance of ICD-10 to MedDRA Mapping which is updated twice per year in June and December 2024 and the development of ICD-11 to MedDRA Mapping.
- ✧ Release of “**MedDRA Points to Consider Companion Document**”, version 3.0 in September 2024.

### **3.7. PQKM Task Force**

Further to the initiative begun by the International Coalition of Medicines Regulatory Authorities (ICMRA), ICH, IPRP and PIC/S to align efforts to support a global regulatory **Pharmaceutical Quality Knowledge Management (PQKM)** capability for chemistry, manufacturing, and controls (CMC) related post approval changes (PACs) submissions, products, and facilities, ICH established a PQKM Technology Platform Task Force (TF) in March 2024 aimed at understanding the technology, legal, operational, and financial considerations needed to establish and govern a **secure standardised technology platform for PQKM**. The PQKM TF was established for 18 months with a main objective to provide the recommendations to be finalised in 2025, which was supported by the launch of a Market Consultation (the Request for Information (RFI) in December 2024 to enable the TF to gather market information.

## 4. 2024 Overview of Meetings & Planning

### 4.1. 2024 Meetings

In 2024, ICH activities were progressed via face-to-face meetings and teleconferences. ICH's biannual meetings see the meeting of WGs for 4-5 days in parallel of Assembly, ICH Management Committee, and MedDRA Management Committee meetings, and are important for progressing ICH's work.

The reports of [Assembly](#) and [ICH Management Committee](#) face-to-face meetings and teleconferences from 2024 are made available on the **ICH website**.

#### Assembly Meetings

- ✧ The **Assembly met twice during 2024**, at the time of ICH's biannual meetings: from 4 to 5 June in Fukuoka, Japan and from 5 to 6 November in Montreal, Canada.
- ✧ 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 Lisbon, Portugal in March 2024
  - ICH Biannual Meeting in Fukuoka, Japan in June 2024
  - ICH Biannual Meeting in Montreal, Canada in November 2024
- ✧ All three meetings were chaired by **Dr. Theresa Mullin (FDA, United States, Chair) and Mr. Naoyuki Yasuda (MHLW/PMDA, Japan, Vice-Chair)**.
- ✧ The ICH Management Committee also met **virtually** throughout the year:
  - **6 times via teleconferences** held on 29 February, 15 April, 7 May, 12 September, 25 September and 10 October.
  - These sessions were well-attended and co-chaired by Dr. Theresa Mullin (FDA, United States, Chair), and 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 20 February, 13 March, 9 April, 11 July, 21 August and 2 October 2024.
  - **2 in-person meetings** during ICH's biannual meeting on 2-3 June and 3-4 November 2024.
- ✧ All meetings in 2024 were chaired by **Dr. Barbee I. Whitaker (FDA, United States, Chair) and/or Dr. Craig Simon (Health Canada, Canada, Vice-Chair)**.

## ICH Working Groups Meetings

The following 13 WGs met in person at the 2024 first biannual meeting with the ICH Management Committee in June 2024:

- E6(R3) - Good Clinical Practice;
- E20 - Adaptive Clinical Trials;
- E21 - Inclusion of Pregnant and Breast-feeding Individuals in Clinical Trials;
- M4Q(R2) - Revision of M4Q(R1) CTD on Quality Guidance;
- M11 - Clinical electronic Structured Harmonised Protocol (CeSHarP);
- M13 - Bioequivalence for Immediate-Release Solid Oral Dosage Forms;
- M15 - General Principles for Model-Informed Drug Development;
- Q1/Q5C - Targeted Revisions of the ICH Stability Guideline Series;
- Q2(R2)/Q14 - Training on Q2(R2): Validation of Analytical Procedures and Q14: Analytical Procedure Development;
- Q3E - Guideline for Extractables and Leachables;
- Q5A(R2) - Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin;
- Q6(R1) - Revision of the Specifications Guidelines;
- Q9(R1) - Quality Risk Management.

During the second biannual meeting in November 2024 the following 12 WGs met in-person:

- E2D(R1) - Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports;
- E6(R3) - Good Clinical Practice;
- E21 - Inclusion of Pregnant and Breast-feeding Individuals in Clinical Trials;
- E22 - General Considerations for Patient Preference Studies;
- M2 - Electronic Standards for the Transfer of Regulatory Information;
- M4Q(R2) - Revision of M4Q(R1) CTD on Quality Guidance;
- M11 - Clinical electronic Structured Harmonised Protocol (CeSHarP);
- M13 - Bioequivalence for Immediate-Release Solid Oral Dosage Forms;
- Q1/Q5C - Targeted Revisions of the ICH Stability Guideline Series;
- Q3E - Guideline for Extractables and Leachables (E&L);
- Q6(R1) - Revision of the Specifications Guidelines;
- CGTDG - Cell and Gene Therapies Discussion Group.

With the ICH Management Committee, one Working Group (WG) held an interim meeting in 2024:

- E11A EWG - Paediatric extrapolation.

Two other WGs held interim meeting during the year; Q13 from 22 to 25 January in Tokyo, Japan and E6(R3) from 4 to 8 March in Basel, Switzerland.

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

## ***4.2. Planning of Future ICH Meetings***

In 2024, 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, along with six WGs in Budapest, Hungary from 13 to 16 March 2025.
- ✧ The ICH Management Committee agreed to continue planning and organising for its next biannual meeting in Madrid, Spain from 10 to 14 May 2025.
- ✧ The ICH Management Committee agreed on proceeding with the planning of the biannual meeting in Singapore from 15 – 19 November 2025.
- ✧ The ICH Management Committee agreed on the following dates for the 2026 and 2027 meetings:
  - 30 May to 3 June 2026 in the Americas – Rio De Janeiro, Brasil
  - 14 to 18 November 2026 in Europe – Istanbul, Türkiye
  - 12 to 16 June 2027 in Asia (country and venue to be confirmed)
- ✧ The ICH Management Committee supported review and additional enhancement of the meeting venue selection criteria to be put forward for the Management Committee consideration in 2025.

## **Professional Conference Organizer (PCO)**

- ✧ 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 2025 in Budapest, Hungary.
- ✧ ICH Management Committee agreed with the support of ICH Assembly to renew the current agreement ICH has with the PCO for the organisation of meetings for a further 3 years covering meetings starting with that in November 2026.

## **5. 2024 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, 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 2024 regarding these documents:

### **ICH Articles of Association**

- ✧ The Assembly approved amendment to the ICH Articles of Association with approval of version 6.0 in November 2024, adding a new article on confidentiality of information.

## **ICH Assembly RoP**

- ✧ The Assembly approved several amendments to the Assembly RoP with approval of version 15.0 in November 2024. Amendments related to: clarification on the meeting participation criterion towards Membership application; revision to the Annex 1: Definitions of terms in the context of the implementation of ICH Guidelines; and amendments further to a new Article 61 on confidentiality of information in the ICH Articles of Association (AoA).

## **ICH Management Committee RoP**

- ✧ The ICH Management Committee approved several amendments to its RoP with approval of version 15.0 in November 2024. Amendments related to: the section 2 of the MC RoP regarding the meeting participation criterion towards MC Elections and section 8 further to a new Article 61 on confidentiality of information in the ICH Articles of Association (AoA).

## **SOPs of the ICH Working Groups**

- ✧ In 2024 the ICH Management Committee supported streamlining the Standard Operating Procedures (SOP) of the ICH Working Groups into 3 separate documents – an Operational Guide for ICH Working Groups, an ICH Coordinators Handbook and an ICH Secretariat Handbook to remove redundancies and processes no longer in practice and create documentation which is user-friendly and fit for purpose. It was agreed that specific Annexes of SOP will be published on the ICH website or relevant SharePoint site standalone documents.

### ***5.2. ICH Operational Efficiency***

In 2024, the ICH Management Committee worked to provide operational support to ICH WGs. This included approval of a revision and streamlining of the ICH Standard Operating Procedure (SOP) into 3 separate documents (see section #5.1).

In addition, following the 2023 Request for Proposal to identify and contract a Technical Writer to support WG Guideline development, in 2024 the ICH Management Committee identified and contracted Technical Writing services provider for the E21 EWG, and approved Technical Writing support for S13 EWG, Q6(R1) EWG and to support the SOP revision.

### ***5.3. ICH Funding***

#### **ICH Financial Audit**

In June 2024 **the Assembly approved the 2023 Audited Accounts and Financial Statements of the ICH Association**, supporting their submission along with ICH's 2023 tax return.

## ICH Funding<sup>1</sup>

2024 Membership Fees were paid as follows by all ICH Members in line with the decision taken by the Assembly in November 2022:

| 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                                |

### *2024 Membership Fees*

The Assembly furthermore approved the fees for 2026, which will be kept at the same level as from 2023.

In November 2024, the Assembly approved the 2025 ICH Association Budget, and noted the 5-Year budget projection for 2025-2029. Information can be found on the [ICH website](#) regarding the 2025 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 2024, **the Assembly approved the 2025 MedDRA Budget, including 2025 MSSO MedDRA Subscription Fees** (unchanged from 2024).

Information can be found on the ICH website regarding the 2025 ICH Association Budget, with information on the MedDRA Subscription Fees available on the MedDRA website.

## Financial Management

In 2024, 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 2024 for 2025 ICH and MedDRA budget preparation and 5-Year ICH and MedDRA budget planning for 2025-2029, 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

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<sup>1</sup> 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.

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 2024:

- ✧ Acknowledging the importance of relevant patient stakeholder engagement in ICH and input from the patient community on ICH Guidelines, an ICH patient session was organised at the DIA Annual Meeting in June 2024, in San Diego, United States, as well as at the DIA Europe meeting in March, in Brussels, Belgium.

#### **ICH Regional Public Meetings**

ICH Members periodically hold dedicated **ICH regional public meetings**, either independently or in collaboration with other non-profit organisations, with an objective to disseminate information on ICH activities. In 2024, ICH Members holding regional public meetings were: FDA, United States with Health Canada, Canada; JPMA; and TFDA, Chinese Taipei.

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 2024 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.

#### **5.6. External Cooperation**

##### **PIC/S**

Further to the Memorandum of Understanding (MoU) with PIC/S (Pharmaceutical Inspection Co-operation Scheme) signed in 2023 and 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, the Management Committee approved funding towards development of the training on ICH Q7, Q9, Q10, Q12, Q13 Guidelines by PIC/S in 2024 as a part of PIC/S Inspectorates' Academy (PIA), with all the training materials developed by PIC/S using ICH funding available for ICH Members and Observers through a dedicated ICH portal.

##### **CIOMS**

In November 2024 the ICH Assembly approved the collaborative agreement with the Council for International Organizations of Medical Sciences (CIOMS), which sets forth the

terms of collaboration between the ICH and CIOMS regarding the sharing and utilisation of the CIOMS Glossary of ICH Terms and Definitions source Excel file with access to be granted solely for internal use by ICH Member and Observers.

## **5.7. ICH Secretariat**

### **2024 Staffing**

The following highlights key points and decisions related to ICH Secretariat staffing in 2024:

- ✧ ICH Secretariat staffing was initially planned at **12 FTEs (Full Time Equivalents) for 2024**, 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 2024, 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 Mr. Florian Bernard** and **Coordinator Mr. Francis Panlilio** join the team May and in August respectively, with **Manager Ms. Nahimeh Jaffar**, **Coordinator Mr. Florian Bernard** and **Director Dr. Dawn Ronan** leaving the ICH Secretariat during the year.
- ✧ In December 2024 the appointment of **Ms. Géraldine Lissalde-Bonnet as Secretary General** of the ICH Secretariat based in Geneva, Switzerland was announced to start in this new position on 12 March 2025.

### **2024 ICH Secretariat Key Activities**

The following outlines key activities undertaken by the ICH Secretariat in 2024 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.

#### **2024 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 November 2024.
- ✧ **Supporting ICH harmonisation activities** and the work of **36 ICH WGs** in 2024, 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: 2023 Annual Report; 2025 ICH Work Plan and ICH Multi-Annual Strategic Plan; and 2025 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 Training Materials, as well as Press Releases.
  - 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 2023 tax return and quarterly VAT declarations; managing ICH's grant agreement with FDA, United States, which in 2024 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.

#### **2024 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 Technical Writer activities** by engaging Technical Writer services provider to support WG Guideline development for ICH E21 EWG.
- ✧ **Managing ICH's Trademark (TM) 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 2024, this effort included the filling and registration of the ICH logo (device) TM in Israel; the registration of the ICH logo (device) TM in Jordan; the registration of the MedDRA (name) TM in Lebanon; the renewal of the MedDRA (name) TM in Maldives (Cautionary Notice) and Philippines (5Y Declaration of Use); the renewal of the MedDRA logo (device) TM in Maldives (Cautionary Notice) and Mexico (3Y Declaration of Use in class 42); 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 as needed.
- ✧ **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.
  - **ICH Secretariat modernisation project** had been initiated in 2024 with a view to reducing administrative burden and workload challenges for the Secretariat and better positioning ICH for the future. These efforts included: developing the Secretariat's technology platform, with an IT Consultant being engaged to advise on this towards developing a strategic plan; optimising the structure and organisation of the Secretariat; and streamlining the procedures. A holistic assessment of the ICH Secretariat IT tools was performed in 2024 and a strategic plan for implementation of new solutions by the end of 2025 was developed with the support of an IT Consultant.
- ✧ **Supporting 4 external organisations in support of the activities and development of permitted daily exposures (PDE) reports** for the development of the Q3E Guideline.
- ✧ **Moving to a new larger office space for the ICH Secretariat**, in April 2024, which include a meeting room for 34 people with a view to being able to host ICH WG interim meetings and other meetings (i.e., ICH Management Committee Sub-Committees).

### ***5.8. ICH & MedDRA Management Committee Appointed Signatories***

At the end of 2024, 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 Ms. Nikoleta Luludi, with Ms. Lucie Archambeau & Ms. Nikoleta Luludi being approved by the MedDRA Management Committee in November 2024 as a new MedDRA signatory in support of MedDRA operations. All signatories have joint (by two) signatory rights.

## Annex I

### ICH Assembly Member Representatives & Observer Delegates

31 December, 2024

#### 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. Stefan Herdinius  
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. Jeffrey Skene

##### ***Swissmedic, Switzerland***

Dr. Andreas Pfenninger  
Dr. Gabriela Zenhausern (*Vice-Chair*)

#### Regulatory Members

##### ***ANMAT, Argentina***

Ms. Andrea Ricchiuti  
Dr. Mariano Saborido

##### ***ANVISA, Brazil***

Ms. Bianca Zimon

##### ***COFEPRIS, Mexico***

Ms. Miriam Jackeline Loera Rosales

##### ***EDA, Egypt***

Dr. Asmaa Fouad

##### ***JFDA, Jordan***

Ms. Rana Ali-ali (Malkawi)  
Dr. Wesal Haqaish

##### ***HSA, Singapore***

Ms. Siew Wei Chua  
Dr. Dorothy Toh

##### ***MFDS, Republic of Korea***

Dr. Sangbong Kim  
Dr. Su Jin Kong

##### ***MHRA, UK***

Ms. Rachel Arrundale  
Ms. Gavia Taan

##### ***NMPA, China***

Dr. Sheng Yang  
Mr. Siyuan Zhou

##### ***SFDA, Saudi Arabia***

Dr. Abdullah Hamad Al Hatareshah  
Dr. Adel Alharf

##### ***TFDA, Chinese Taipei***

Dr. Jo-Feng Chi  
Ms. Mei-Chen Huang

##### ***TITCK, Turkey***

Ms. Elif İnci Ergönül  
Ms. Handan Öztunca

## **Industry Members**

### **BIO**

Dr. Wassim Nashabeh  
Dr. Derek Scholes

### **Global Self-Care Federation**

Dr. Padmaja Kamath  
Ms. Judy Stenmark

### **IGBA**

Dr. Nick Cappuccino  
Ms. Beata Stepniewska

## **Standing Observers**

### **IFPMA**

Ms. Ginny Beakes-Read  
Ms. Flavia Firmino

### **WHO**

Dr. Samvel Azatyan  
Mr. Hiiti B. Sillo

## **Observers**

### **AEC, Azerbaijan**

Mr. Farid Hasanov

### **ANPP, Algeria**

Dr. Amel Bensedira

### **APEC**

Dr. Younjoo Park

### **APIC**

Ms. Luisa Paulo

### **ASEAN**

Ms. Worasuda Yoongthong

### **CDSCO, India**

Dr. Rajeev Singh Raghuvanshi

### **CECMED, Cuba**

Dr. Celeste Sánchez González

### **CIOMS**

Dr. Lembit Rägo

### **CPED, Israel**

Dr. Ofra Axelrod

### **CPPS, Uzbekistan**

Mr. Alisher Temirov

### **DIGEMID, Peru**

Ms. Cory Montero Suyo

### **DPM, Tunisia**

Prof. Abderrazek Hedhili

### **EAC**

Mr. Felchism Apolnary Oisso

### **EDQM**

Dr. Petra Doerr

### **GHC**

Mr. Othman Alsaleh

### **Gates Foundation**

Dr. Murray LumpkinGHC  
Mr. Othman Alsaleh

### **Indonesian FDA, Indonesia**

Ms. Tri Asti Isnariani

### **INVIMA, Colombia**

Ms. Yenny Marcela Suárez González

### **IPEC**

Ms. Janeen Skutnik-Wilkinson

### **MMDA, Moldova**

Mr. Dragoş Guţu

### **MOPH, Lebanon**

Dr. Colette Raidy

### **NAFDAC, Nigeria**

Prof. Christianah Mojisola Adeyeye

### **National Center, Kazakhstan**

Prof. Shynar Baidullayeva

### **NPRA, Malaysia**

Dr. Azuana Ramli

### **NRA, Iran**

Dr. Mahmoud Alebouyeh

### **PANDRH**

Ms. Maria Luz Pombo-Castro

**PIC/S**

Mr. Jeffrey Hodgson

**PPBHK, Hong Kong, China**

Mr. Frank Chan Ling-Fung

**Rosdravnadzor, Russia**

Ms. Anastasia Nikitina

**SADC**

Ms. Fortunate Ntombi Bhembe

**SAHPRA, South Africa**

Ms. Silverani Padayachee

**SCDMTE, Armenia**

Dr. Lilit Ghazaryan

**SECMOH, Ukraine**

Dr. Mykhailo Babenko

**TGA, Australia**

Mr. Michael Wiseman

**Thai FDA, Thailand**

Dr. Chaiporn Pumkam

**USP**

Dr. Kevin Moore

## Annex II

### ICH Management Committee Representatives

December 31, 2024

#### Founding Regulatory Members

##### *EC, Europe*

Dr. Milton Bonelli  
Ms. Lenita Lindström

##### *FDA, United States*

Mr. Andrew Kish  
Dr. Michelle Limoli  
Dr. Theresa Mullin (*Chair*)

##### *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 Zenhäusern

##### *Health Canada, Canada*

Mr. Jeffrey Skene

#### Standing Observers

##### *WHO*

Dr. Samvel Azatyan  
Mr. Hiiti B. Sillo

##### *IFPMA*

Ms. Ginny Beakes-Read  
Ms. Flavia Firmino

#### Regulatory Members

##### *ANVISA, Brazil*

Ms. Bianca Zimon

##### *MFDS, Republic of Korea*

Dr. Sangbong Kim  
Dr. Su Jin Kong

##### *NMPA, China*

Dr. Sheng Yang  
Mr. Siyuan Zhou

##### *SFDA, Saudi Arabia*

Dr. Abdullah Hamad Al Hatareshah  
Dr. Adel Alharf

#### Industry Members

##### *BIO*

Dr. Wassim Nashabeh  
Dr. Derek Scholes

##### *IGBA*

Dr. Nick Cappuccino  
Ms. Beata Stepniewska

## **Annex III**

### **MedDRA Management Committee Representatives**

31 December, 2024

#### **Founding Regulatory Members**

##### ***EC, Europe***

Dr. Georgios Balkamos  
Dr. Ana Cochino

##### ***FDA, United States***

Dr. Barbee I. Whitaker (*Chair*)  
Mr. Ranjit Thomas

##### ***MHLW/PMDA, Japan***

Mr. Masahiro Inada  
Mr. Masahiro Takahata

#### **Founding Industry Members**

##### ***EFPIA***

Mr. Vitali Chevts  
Mr. Christopher Golds

##### ***JPMA***

Ms. Mamiko Kasho (Konishi)  
Ms. Yasuyo Suzuki

##### ***PhRMA***

Dr. Maria Apostolaros  
Mr. Raymond Kassekert

#### **Standing Regulatory Member**

##### ***Health Canada, Canada***

Dr. Craig Simon (*Vice-Chair*)

#### **Regulatory Members**

##### ***MHRA, UK***

Ms. Charlotte James  
Mr. Philip Tregunno

#### **Standing Observers**

##### ***WHO***

Mr. Fumihito Takanashi

## **Annex IV**

### **ICH Secretariat Staff**

31 December, 2024

#### **Director of Operations**

Ms. Nikoleta Luludi

#### **Senior Manager**

Ms. Emilie Macara

#### **Managers**

Ms. Lucie Archambeau

Mr. Sivashen Cunden

Ms. Petra Grand

#### **Senior Coordinator**

Ms. Anca-Elena Matei

#### **Coordinators**

Mr. David Demyttenaere

Mr. Francis Panlilio

#### **Administrative Assistants**

Ms. Amina Mir

Ms. Charlotte Rémié

## Annex V

### Assembly Member and Standing Observer ICH Coordinators

31 December, 2024

#### Founding Regulatory Members

##### ***EC, Europe***

Dr. Georgios Balkamos

Dr. Kevin Cunningham (Technical Coordinator)

##### ***MHLW/PMDA, Japan***

Ms. Yasuko Inokuma

Dr. Takashi Misu (Technical Coordinator)

##### ***FDA, United States***

Ms. Jill Adleberg

Dr. Marijo Kambere (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

##### ***ANMAT, Argentina***

Ms. Sabrina Filipic Ozurovic

##### ***ANVISA, Brazil***

Ms. Balbiana Verazez Sampaio Oliveira

##### ***COFEPRIS, Mexico***

Ms. Margarita Contreras Olvera

##### ***EDA, Egypt***

Dr. Sondos Moshtohry

##### ***HSA, Singapore***

Ms. Shu Yi Ong

##### ***JFDA, Jordan***

Ms. Enas Hijjeh

##### ***MFDS, Republic of Korea***

Ms. Mirinea Kim

##### ***MHRA, UK***

Mr. Gordon Wood

##### ***NMPA, China***

Dr. Yu Bai

##### ***SFDA, Saudi Arabia***

Mr. Nawaf M. Almotairi

##### ***TFDA, Chinese Taipei***

Ms. Yi-Ju Lin

##### ***TITCK, Turkey***

Dr. Elif İnci Ergönül

#### Industry Members

##### ***BIO***

Ms. Mr. Neil Ichiro Laruan

##### ***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 2024

| 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                                                                          |                                                                            | Training Module I, II, III are expected shortly                                                  |
| E2D(R1)             | EWG        | Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports | Step 2 reached in February 2024                                            | Step 4 expected May 2025                                                                         |
| E6(R3)              | EWG        | Good Clinical Practice                                                                                              | Step 2 reached in November 2024 (Annex 2)                                  | Step 4 expected in January 2025 (Principles & Annex 1)<br>Step 4 expected by June 2025 (Annex 2) |
| E11A                | EWG        | Paediatric Extrapolation                                                                                            | Step 4 reached in August 2024                                              | Training Materials expected by August 2025                                                       |
| E14/S7B             | IWG        | Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential                     | Reactivation of the E14/S7B IWG in March 2024 to develop second-round Q&As | Step 4 is expected by November 2025 (second-round Q&As)                                          |
| E20                 | EWG        | Adaptive Clinical Trials                                                                                            |                                                                            | Step 2 is expected shortly                                                                       |
| E21                 | EWG        | Inclusion of Pregnant and Breastfeeding                                                                             |                                                                            | Step 2 is expected by Q1/Q2 2025                                                                 |

| Topic Code | Type of WG          | Topic Name                                                                                                            | Accomplishments                                                                                                                                                                                                         | Anticipated Milestones                                                                                                                                      |
|------------|---------------------|-----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                     | Individuals in Clinical Trials                                                                                        |                                                                                                                                                                                                                         |                                                                                                                                                             |
| E22        | EWG                 | General Considerations for Patient Preference Studies                                                                 | Concept Paper approved in June 2024                                                                                                                                                                                     | Step 2 is expected by December 2025                                                                                                                         |
| M1         | PtC WG              | MedDRA Points to Consider                                                                                             | Release of Companion document v3.0 with a new section on “Manufacturing and quality system issues” and revised sections on Introduction, Data quality, Medication errors, and Product quality issues in September 2024. | Release of updated “MedDRA Term Selection” and “MedDRA Data Retrieval and Presentation” PtC documents expected in March 2025 (based on MedDRA Version 28.0) |
| M2         | EWG                 | Electronic Standards for the Transfer of Regulatory Information (ESTRI)                                               | Release of JSON M2 Recommendation in May 2024                                                                                                                                                                           | Release of Emerging Technologies Assessment expected in 2025                                                                                                |
| M4Q(R2)    | EWG                 | Common Technical Document on Quality Guideline                                                                        |                                                                                                                                                                                                                         | Step 2 is expected by May 2025                                                                                                                              |
| M7(R3)     | Maintenance EWG/IWG | Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk |                                                                                                                                                                                                                         | N/A (Ongoing Activity)                                                                                                                                      |
| M7         | Sub-Group           | Risk Assessment and Control of Nitrosamine Impurities                                                                 | M7 Sub-group was established in August 2024                                                                                                                                                                             | M7 Sub-group continues to develop Concept Paper                                                                                                             |

| Topic Code | Type of WG | Topic Name                                                                                                  | Accomplishments                                                                                            | Anticipated Milestones                                                                                                                                                                        |
|------------|------------|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| M8         | EWG/IWG    | The Electronic Common Technical Document (eCTD)                                                             |                                                                                                            | <i>Step 4</i> is expected shortly for the ICH M8 eCTD 3.2.2 Q&As v1.34 and eCTD 4.0 Q&As v1.9                                                                                                 |
| M10        | EWG        | Bioanalytical Method Validation and Study Sample Analysis                                                   | Release of M10 Training Material in February 2024 following which the M10 EWG was disbanded                | N/A                                                                                                                                                                                           |
| M11        | EWG        | Clinical electronic Structured Harmonised Protocol (CeSHarP)                                                |                                                                                                            | <i>Step 4</i> is expected by November 2025 (Guideline, Template and Technical Specification) and Fast Healthcare Interoperability Resources (FHIR) Technical Implementation Guide by May 2026 |
| M12        | EWG        | Drug Interaction Studies                                                                                    | <i>Step 4</i> was reached for the M12 Guideline and Q&As in May 2024 following which the EWG was disbanded | N/A                                                                                                                                                                                           |
| M13        | EWG        | Bioequivalence for Immediate-Release Solid Oral Dosage Forms                                                | <i>Step 4</i> was reached for the M13A Guideline and M13A Q&As in July 2024                                | <i>Step 2</i> is expected by March 2025 (M13B)                                                                                                                                                |
| M14        | EWG        | General principles on plan, design, and analysis of pharmacoepidemiological studies that utilize real-world | <i>Step 2</i> was reached for the M14 Draft Guideline in May 2024                                          | <i>Step 4</i> is expected by June 2025                                                                                                                                                        |

| Topic Code | Type of WG      | Topic Name                                                                                          | Accomplishments                                                          | Anticipated Milestones                        |
|------------|-----------------|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-----------------------------------------------|
|            |                 | data for safety assessment of medicine                                                              |                                                                          |                                               |
| M15        | EWG             | General Principles for Model-Informed Drug Development                                              | Step 2 was reached for the M15 Draft Guideline in November 2024          | Step 4 is expected in Q4 2025                 |
| Q1/Q5C     | EWG             | Targeted Revisions of the ICH Stability Guidelines Series                                           |                                                                          | Step 2 is expected by Q1 2025                 |
| Q2(R2)/Q14 | IWG             | Training on Q2(R2): Validation of Analytical Procedures and Q14: Analytical Procedure Development   |                                                                          | Training Materials are expected by March 2025 |
| Q3C(R10)   | Maintenance EWG | Maintenance of the Guideline for Residual Solvents                                                  |                                                                          | Step 2 is expected by October 2025            |
| Q3D(R3)    | Maintenance EWG | Maintenance of the Guideline for Elemental Impurities                                               |                                                                          | N/A (Dormant state)                           |
| Q3E        | EWG             | Guideline for Extractables and Leachables                                                           |                                                                          | Step 2 is expected by June 2025               |
| Q5A(R2)    | IWG             | Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin |                                                                          | Training materials are expected shortly       |
| Q6(R1)     | EWG             | Revision of the Specifications Guidelines                                                           | Concept Paper approved in July 2024                                      | Step 2 is expected by June 2026               |
| Q9(R1)     | Training Group  | Quality Risk Management                                                                             | Release of Q8/Q9/Q10 training material in November 2024 and transitioned | Q9 Briefing Pack Training Materials are       |

| Topic Code | Type of WG | Topic Name                                                                                          | Accomplishments                                                                             | Anticipated Milestones                                         |
|------------|------------|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|----------------------------------------------------------------|
|            |            |                                                                                                     | to a Q9(R1) Training Group                                                                  | expected by September 2025                                     |
| Q12        | IWG        | Training on Regulatory and Technical Considerations for Pharmaceutical Product Lifecycle Management | Release of Training Material Module 8 in February 2024                                      | N/A (Dormant state)                                            |
| Q13        | IWG        | Continuous Manufacturing of Drug Substances and Drug Products                                       | Release of Q13 Training Material in November 2024 following which the Q13 IWG was disbanded | N/A                                                            |
| S1B(R1)    | IWG        | Training on Testing for Carcinogenicity of Pharmaceuticals                                          | Concept Paper approved in March 2024 and transitioned to IWG                                | Conclusion of implementation monitoring expected by March 2027 |
| S13        | EWG        | Nonclinical Safety Studies for Oligonucleotide-Based Therapeutics                                   | Final S13 Concept Paper approved in November 2024                                           | Step 2 is expected by October 2026                             |
| CGTDG      | DG         | Cell and Gene Therapies Discussion Group                                                            |                                                                                             | Recommendation paper expected by October 2025                  |
| GDG        | DG         | Generic drug Discussion Group                                                                       | Disbandment in June 2024                                                                    | N/A                                                            |
| QDG        | DG         | Quality Discussion Group                                                                            |                                                                                             | N/A (Ongoing activity)                                         |