

ICH Association

Multi-Annual Strategic Plan

Version dated 30 October 2025

Approved by the Assembly on 18 November 2025

The following table highlights the key areas of work foreseen for the ICH Association:

Category	Description
Strategy	✧ Continue review and planning of already identified strategic priorities and assess potential new areas of opportunity for the ICH Association ✧ Promote ICH Guidelines implementation by Regulatory Members and Observers, and encourage implementation of ICH Guidelines by other Drug Regulatory Authorities and Regional Harmonisation Initiatives. Consider improvements to the established sustainable ICH-driven mechanism to assess implementation and adherence to the ICH Guidelines ✧ Continue implementation of a strategic approach to address ICH Guideline training needs ✧ Continue multi-year budget planning to ensure sound financial management of the ICH Association's funds, whilst also ensuring the ongoing operational stability of the ICH Association ✧ Continue activities related to the modernisation of the ICH Secretariat, including developing the Secretariat's technology platform and streamlining the procedures.
Harmonisation	✧ Progress harmonisation activities on all approved ICH topic proposals – Annex I provides a multi-year overview of harmonisation activities on current ICH topics ✧ Assess / approve on a regular basis proposals for new ICH topics according to the agreed process in order to keep an ongoing stream of harmonisation activities based on the total number of concurrent technical Working Groups (WGs) which the Association can support at a given time
Communication	✧ Continue implementation of approved transparency policy with continued improvements as appropriate to ensure continuously enhanced communication with stakeholders

Category	Description
Procedures	✧ Maintain / update as necessary the Rules of Procedure (RoP) for the Assembly, the Management Committee, the MedDRA Steering Committee and Standard Operating Procedure (SOPs) of the ICH WGs to ensure the continued smooth operation of the ICH Association as it continues to grow and evolve
Operations	✧ Continue ICH-driven mechanism to assess implementation and adherence to the ICH Guidelines through surveying and results analysis ✧ Continue developing the ICH training strategy in line with the approach of creating online training materials for all ICH Guidelines and offering tailored training. ✧ Process / decide on applications for ICH Membership and Observership according to the ICH Articles of Association (AoA) ✧ Organise annual audits of the Association's accounts and ensure the meeting of fiscal reporting requirements for ICH Association ✧ Continue implementation of sustainable, consistent and cost-efficient approach for the ICH Association's organisation of biannual ICH meetings ✧ Register the ICH logo as a trademark in ICH Member and Observer countries/regions taking account of new Members and Observers joining ICH

*For an overview of planned harmonisation activities, see the latest accompanying **Multi-year Overview of Harmonisation Activities (2026-2029)**.*