

MedDRA Steering Committee

2026 Annual Work Plan

(1 January – 31 December 2026)

2026 Work Plan

The following table summarises the key MedDRA work items for the MedDRA Steering Committee planned in 2026:

Category	Description	Anticipated Timeline
Strategy	 Ensure MedDRA's continued responsiveness to the needs of global MedDRA users, facilitating necessary changes to the terminology in a timely manner to enable scientific and medical information to be captured, shared and analysed appropriately, and adapting services such as training and communication to enable high-quality virtual support to MedDRA users;  Continue to identify opportunities to expand and support MedDRA's global reach through extended MedDRA training opportunities, provision of MedDRA Maintenance and Support Services Organisation (MSSO) local in-country/region support; consideration of new MedDRA translation requests; and ensuring assistance to Regulators and MedDRA users in regions newly transitioning to MedDRA e.g., Africa, Asia, Eurasia, Latin America, Middle East;  Promote continued coordination with other international organisations, including IMDRF, SNOMED International and WHO, to support interoperability between their terminologies and MedDRA to facilitate data exchange, conversion and analysis by Regulatory and Industry stakeholders;  Continue to oversee the implementation of activities towards a digital transformation of MSSO operations and services leveraging technological developments, such as Artificial Intelligence (AI) / Machine Learning (ML), to ensure maximised efficiency of MSSO activities and optimised support of MedDRA users;	Ongoing in 2026

	 Ensure the sound financial oversight of MedDRA activities in close coordination with the ICH Management Committee through participation in the ICH Finance Committee to further ICH's goals while ensuring longer term operational stability and sustainability;  Implement proactive processes to address potential interruptions across various scenarios, to ensure the current high level of functionality which MedDRA users have come to expect.	
Operations	 Oversee the activities of the MSSO including MedDRA development activities and support of MedDRA users, including the following MSSO activities: ○ Managing development, review and finalization for release to MedDRA users of new MedDRA translations including: Bulgarian, Danish, Maltese, and Romanian, in coordination with EC, Europe and the respective Member State Regulatory Authorities; and Uzbek; ○ Conducting training to support MSSO's global Subscribers, including Regulators, through face-to-face training, live webinar training, and on-demand e-training; ○ Ensuring global support for MSSO Subscribers as more countries/regions transition to MedDRA by leveraging the MSSO local support staff, and continuing to provide local support in Latin America, Africa/Middle East, China, Republic of Korea, India, and Russia; ○ Strengthening the capacity of African regulatory authorities through MedDRA training, thereby enhancing medical product vigilance across all African countries; ○ Coordinating with SNOMED International regarding the maintenance and distribution of the bidirectional mapping between SNOMED CT and MedDRA; ○ Supporting WHO and ICH collaboration to provide the interoperability between ICD-10/11 and MedDRA terms with a unidirectional ICD-10 to MedDRA mapping already released, and with a bidirectional MedDRA ↔ ICD-11 under development; ○ Supporting the maintenance of the mapping between MedDRA and IMDRF terms; ○ Managing ongoing maintenance of Standardised MedDRA Queries (SMQs) and <i>ad hoc</i> development of any new SMQ, including applying AI techniques to the SMQ MedDRA maintenance process; ○ Supporting the work of the ICH MedDRA Points to Consider (PtC) Working Group (WG) to update the PtC documents on Term Selection and Data Retrieval & Presentation and release the Companion document v4.0 with additional guidance on terms relating to Manufacturing and Quality System Issues relevant to large molecule, biologics, vaccines, and drug delivery devices; ○ Maintaining and enhancing MSSO IT tools and systems to improve both MedDRA user tools and internal tools to increase efficiency;	Ongoing in 2026

	○ Discussing MedDRA's use with regulatory authorities, major stakeholders or subscribers and whether MedDRA meets their needs; ○ Promoting MedDRA to external stakeholders; ○ Following the work of other global initiatives of relevancy for MedDRA activities such as ISO, MFAET, IDMP.	
	 Oversee the selection of auditors as part of multi-year audit plan covering financial, IT, clinical & procedural aspects, and conduct of audits in line with planning.	Ongoing in 2026
	 Issue advice to the ICH Management Committee regarding the objectives, responsibilities, and scope of authority of the ICH Secretariat in as far as MedDRA activities are concerned.	Ongoing in 2026
	 Ensure worldwide protection of MedDRA's Intellectual Property.	Ongoing in 2026
	 Issue advice to the ICH Management Committee regarding proposals for cooperation with other organisations and contracts with third parties which are necessary to the maintenance, development and strategic placement of MedDRA, or which are necessary to its oversight of MSSO activities.	Ongoing in 2026
	 Submit to the ICH Management Committee the 2025 annual report on the activities of the MedDRA Steering Committee, which should be incorporated into the annual report on the activities of the ICH Association for subsequent Assembly approval.	May 2026
	 Submit to the ICH Management Committee the 2027 work plan on the activities of the MedDRA Steering Committee for subsequent Assembly approval.	October 2026
	 Ensure MedDRA's integrity as a harmonised standard and MedDRA's viability and sustainability.	Ongoing in 2026
	 Ensure a good working relationship between the MSSO and the JMO to meet the needs of MedDRA users in Japan and ensure harmonisation in the offerings provided to MSSO and JMO subscribers.	Ongoing in 2026
Procedures	 Revise and maintain as necessary the Rules of Procedure for the MedDRA Steering Committee, while keeping the ICH Management Committee informed, in accordance with the Articles of Association.	Ongoing in 2026
Financial	 Approve 2027 MSSO Business Plan.	November 2026
	 Issue advice to the ICH Management Committee for the 2027 subscription fees for MedDRA, in collaboration with the ICH Finance Committee, and as part of the 2027 annual budget for MedDRA, that is incorporated in the annual	November 2026

	budget of the Association. This includes maintaining a 5-year budget plan in line with MedDRA strategic and administrative multi-year planning.	
Election	 Conduct a new election for the MedDRA Steering Committee Vice-Chair.	November 2026