

## MedDRA Management Committee








### 2019 Annual Work Plan

(1 January – 31 December 2019)

#### 2019 Work Plan

The following table summarises the key MedDRA work items for the MedDRA Management Committee planned in 2018:

Category	Description
Operations	 Oversee the activities of the MedDRA Maintenance and Support Services Organisation (MSSO) including MedDRA development activities and support of MedDRA users, including the following MSSO activities: <ul style="list-style-type: none"> <li>○ Managing review and finalization for release to MedDRA users of a Korean MedDRA translation the draft of which was developed by ICH Regulatory Member MFDS, Republic of Korea;</li> <li>○ Managing review and finalization for release to MedDRA users of a Russian MedDRA translation in close coordination with ICH Regulatory Observer Roszdravnadzor, Russia;</li> <li>○ Managing development of a Brazilian MedDRA translation in close coordination with ICH Regulatory Member ANVISA, Brazil;</li> <li>○ Conducting training for MSSO Subscribers, including Regulators in Europe, US, China and other regions upon request;</li> <li>○ Ensuring global support for MSSO Subscribers as more countries and regions commence use of MedDRA, including by providing local support in China, Republic of Korea, India and Latin America;</li> <li>○ Providing assistance to Regulators expressing interested in MedDRA or in having a MedDRA translation in their national language;</li> </ul>

	<ul style="list-style-type: none"> <li>○ Collaborating with the Innovative Medicines Initiative (IMI) Web-RADR2 project partners to progress a mapping methodology and provide a Proof-of-Concept mapping between MedDRA and SNOMED;</li> <li>○ Investigating MedDRA interoperability with ICD 10/11;</li> <li>○ Collaborating with ICH Observer the Council for International Organizations of Medical Sciences (CIOMS) on the development and maintenance of Standardised MedDRA Queries (SMQs);</li> <li>○ Supporting the work of the ICH MedDRA Points to Consider (PtC) Working Group (WG) to update with each MedDRA release the PtC documents on <i>Term Selection</i> and <i>Data Retrieval &amp; Presentation</i>, and as necessary, the companion document to the PtC documents;</li> <li>○ Maintaining and enhancing MSSO IT tools;</li> <li>○ Promoting MedDRA to external stakeholders.</li> </ul>
	<ul style="list-style-type: none"> <li> Provide oversight and direction to the MedDRA Secretariat</li> </ul>
	<ul style="list-style-type: none"> <li> Ensure worldwide protection of MedDRA's Intellectual Property</li> </ul>
<b>Procedures</b>	<ul style="list-style-type: none"> <li> Maintain as necessary the Rules of Procedure for the MedDRA Management Committee</li> </ul>
	<ul style="list-style-type: none"> <li> Consider the need to extend the Memorandum of Understanding with CIOMS for the development of SMQs</li> </ul>
<b>Financial</b>	<ul style="list-style-type: none"> <li> Approve 2020 MSSO Business Plan and Budget</li> </ul>
	<ul style="list-style-type: none"> <li> Determine 2020 MSSO Subscription fees</li> </ul>
	<ul style="list-style-type: none"> <li> Present to the Assembly for approval the 2020 Budget for MedDRA, including 2020 Subscription fees, based on strategic multi-year planning</li> </ul>