

Medical Dictionary for Regulatory Activities (MedDRA) Maintenance and Support Services Organization (MSSO)

MedDRA®: How It All Started

For years, a single, globally accepted terminology has been needed, by regulatory authorities and industry alike, for all communications associated with registering, documenting, and safety monitoring of medical products. This great, growing need prompted the development of MedDRA in the early 1990s under the auspices of the International Conference on Harmonization of Technical Requirements or Registration of Pharmaceuticals for Human Use (ICH). Since then, MedDRA has been rigorously refined, expanded, and tested. Worldwide, regulatory agencies are committed to its use.

The long-term success of MedDRA depends on effective maintenance and update support to ensure that the terminology continues to evolve and meet user requirements. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) acting as a trustee for ICH, contracted with Northrop Grumman to provide the MedDRA Maintenance and Support Services Organization (MSSO). The MSSO reports to IFPMA and an ICH Board of Directors.

MedDRA Spoken Here

MedDRA (Medical Dictionary for Regulatory Activities) is the global standard medical terminology for adverse event reporting and analysis.

Major global regulatory authorities in the United States, Europe, and Japan have adopted MedDRA and have required its use. The FDA, for example, has implemented MedDRA within its Adverse Event Reporting System (AERS). European and Japanese regulators have mandated the use of MedDRA for clinical trials and for marketed product reporting. Most regulatory authorities are using MedDRA as a required part of their electronic submission systems.

The MSSO is responsible for ensuring the terminology is updated regularly and that it remains responsive to user needs. The MSSO is committed to the global success of MedDRA.

MedDRA is intended for use by:

- Pharmaceutical companies
- Biotechnology companies
- Device manufacturers
- Regulatory authorities
- CROs
- System developers
- Other support service organizations

How Do You Use MedDRA?

The first step toward MedDRA implementation is to subscribe to MedDRA. The annual subscription includes periodic updates. Subscribers may request changes to the terminology and gain other important benefits including help desk support and user group membership.

What Support Is Available from the MSSO?

The MSSO offers a wide range of orientation, assessment, training, coding, and implementation support to ensure that each new subscriber achieves a smooth, efficient, and cost-effective transition and implementation. Please contact the MSSO for more detailed information.

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Profiling the MSSO

Northrop Grumman has a long association with MedDRA, including playing an instrumental role in revising and extending the original version of the terminology. To learn about MedDRA and how the MSSO can support you, contact us today by email at mssohelp@ngc.com or visit our website www.meddramsso.com.