

The Medical Dictionary for Regulatory Activities (MedDRA) Terminology is a registered trademark of the International Federation of Pharmaceutical Manufacturers Associations. The Authorities encourage companies to use this dictionary. This terminology is developed under the auspices of the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use and it is provided and maintained by the MSSO (MedDRA Maintenance Services Support Organization). This new international medical terminology is particularly important for the electronic transmission of adverse events reporting, both in the pre- and post- marketing areas, as well as in the coding of clinical trial data. It is a new standard dictionary that can be used for the coding of Adverse Drug Reactions, Adverse Events, Medical History, Social History and Indications. It has already been adopted by all regulatory agencies and regulators. It has been developed for many reasons:

- No availability of an internationally accepted medical terminology for regulatory purposes:
  - In Europe, many Organizations use a combination of the World Health Organization's Adverse Reaction Terminology (WHO-ART) and the International Classification of Diseases Ninth Revision (ICD-9).
  - In the United States, the Food and Drug Administration (FDA's) Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART) is usually used in conjunction with Clinical Modification of ICD-9.
  - The Japanese developed their own versions of these international terminologies, Japanese Adverse Reaction Terminology (J-ART) and MEDIS.
- Lack of specificity of terms
- Limited data retrieval options
- Development of non-standard terminologies
- Inability to support exchange data
- Lack of standardized codes
- Lack of international maintenance

Many Organizations have developed their own terminologies. Using different terminologies in separate geographic regions impairs international communication and necessitates the conversion of data from one terminology to another. This data conversion causes time delays and inevitable loss or distortion of data. The use of multiple terminologies also affects communication between companies and clinical research organizations.

The MedDRA is

- a clinically-validated medical terminology.
- Applicable to all phases of drug development (including biologicals but excluding animal toxicology).
- designed for regulatory authorities and the regulated pharmaceutical industry.
- used in the full regulatory process, from pre-marketing to post-marketing as follows:
  - clinical studies
  - reports of spontaneous adverse reactions and events
  - regulatory submissions
  - regulated product information

MedDRA includes:

- signs
- symptoms
- diseases
- diagnoses
- therapeutic indications
- names and qualitative results of investigations, including pharmacokinetics
- surgical and medical procedures
- medical/social/family history

The MedDRA Terminology Includes References to Other Terminologies:

- J-ART (1996) Preferred Terms, Included Terms
- COSTART (Fifth Edition) Preferred Terms, Glossary Terms
- HARTS . (Release 2.2)

The terminology was not developed as a metathesaurus and the hierarchies of these other terminologies are not subsets of it. Thus, data entry terms from other terminologies do not necessarily have the same PT (Preferred Term) in the MedDRA terminology as they did in their “parent” terminology. The hierarchies used for data retrieval and presentation are unique to MedDRA.

The following terms used in regulatory affairs are out of scope:

- Drug/product terminology
- Equipment/device/diagnostic product terminology Study design
- Demographics (including patient sex, age, race and religion)

As its focus is on health effects in individual patients, the following are excluded:

- Failure of devices (except for a small number of clinically relevant terms)
- Qualifiers that refer to populations rather than individual patients, e.g., rare, frequent

Other Exclusions:

- Numerical values associated with parameters are not included.
- Degrees of severity are not included in the terminology. Terms such as severe and mild are used only when pertinent to the specificity of the term (e.g., severe versus mild mental retardation).