



ICH Best Practice Approaches for using MedDRA

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for Registration of Pharmaceuticals for Human Use

ICH-endorsed guides for MedDRA users

- ***MedDRA Term Selection: Points to Consider (MTS:PTC)***
- ***MedDRA Data Retrieval and Presentation: Points to Consider (DRP:PTC)***

Points to Consider Documents

- **Developed by a working group of the ICH Steering Committee**
 - Regulators and industry representatives
 - EU, Japan, USA
 - Canadian observer, MSSO, JMO
- **Updated twice yearly with each MedDRA release**
- **Available on MSSO, JMO, and ICH Web sites**
 - English and Japanese
 - Variety of file formats for ease of viewing and editing
 - Summary of Changes document

MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.5
Based on MedDRA Version 16.0

1 April 2013

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selection to facilitate a
common understanding
of shared data

Term Selection Points to Consider

General Term Selection Principles

Quality of Source Data

Term Selection points

Versioning

Term Selection Points - Examples

- **Diagnoses and Provisional Diagnoses with or without Signs and Symptoms**
- **Death and Other Patient Outcomes**
- **Suicide and Self-Harm**
- **Combination Terms**
- **Exposures During Pregnancy and Breast Feeding**
- **Congenital Terms**
- **Neoplasms**
- **Medical and Surgical Procedures**
- **Investigations**
- **Off Label Use**
- **Misuse, Abuse and Addiction**

Example from Term Selection PtC

3.5.4 When to “split” into more than one MedDRA term

If “splitting” the reported ARs/AEs provides more clinical information, select more than one MedDRA term.

Example

Reported	LLT Selected
Diarrhea and vomiting	Diarrhea Vomiting
Wrist fracture due to fall	Wrist fracture Fall

Points of Note

- **In some cases with more than one option for selecting terms, a “preferred option” is identified but this does not limit MedDRA users to applying that option. Organizations should be consistent in their choice of option.**

MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER

**ICH-Endorsed Guide for MedDRA Users
on Data Output**

***Release 3.5
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• Provides data retrieval and presentation options for industry, regulatory authorities, public health organisations and

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Guidance on MedDRA
Term Selection: Points to
Consider document

DRP:PTC Points Addressed

- **General Queries and Retrieval**
 - General Principles
 - Overall Presentation of Safety Profiles
- **Standardised MedDRA Queries**
 - Comprehensive overview including applications and search options
- **Customized Searches**
 - Modified MedDRA Query Based on an SMQ
 - Customized Queries

Current membership of M1 PtC

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Commission of the European Communities	Sarah Vaughan
	Maria Luisa Casini
European Federation of Pharmaceutical Industries Associations	Hilary Vass*
	Christina Wintert†
Health Canada	Alison Bennett
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Thank You!

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