Introduction to the
Points to Consider Documents
MedDRA was developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Board, which is composed of the six ICH parties (EU, EFPIA, MHLW, J PMA, FDA, PhRMA), the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).
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Points to Consider Documents

• ICH-endorsed guides for MedDRA users
• MedDRA Term Selection: Points to Consider (MTS: PTC)
• MedDRA Data Retrieval and Presentation: Points to Consider (DRP: PTC)
• Recommended to be used as the basis for individual organizations’ coding and retrieval conventions
Points to Consider Documents (cont)

- 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 Points to Consider

MedDRA Term Selection: Points to Consider Document

ENGLISH

- ENGLISH Release 4.4 (pdf) Based on MedDRA Version 15.1
- ENGLISH Release 4.4 (.docx)
- ENGLISH Release 4.4 (web-based)
- Summary of Changes from Release 4.3 (pdf)
- Summary of Changes from Release 4.3 (.docx)

JAPANESE

- JAPANESE Release 4.4 (.docx)
- JAPANESE Release 4.4 (web-based)
- Summary of Changes from Release 4.3 (pdf)
- Summary of Changes from Release 4.3 (.docx)

MedDRA Data Retrieval and Presentation: Points to Consider Document

ENGLISH

- ENGLISH Release 3.4 (pdf) Based on MedDRA Version 15.1
- ENGLISH Release 3.4 (.docx)
- ENGLISH Release 3.4 (web-based)
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- JAPANESE Release 3.4 (.docx)
- JAPANESE Release 3.4 (web-based)
- Summary of Changes from Release 3.3 (pdf)
- Summary of Changes from Release 3.3 (.docx)

Please email any questions to: MSSO Help Desk or call at +1 877.258.8280.

PTC Archive
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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• Provides term selection advice for industry and regulatory purposes

• Objective is to promote accurate and consistent term selection to facilitate a common understanding of shared data
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.

• Section 4.1 – Versioning (Appendix)
  – 4.1.1 Versioning methodologies
  – 4.1.2 Timing of version implementation
General Term Selection Principles

• Quality of Source Data
• Quality Assurance
• Do Not Alter MedDRA
• Always Select a Lowest Level Term
• Select Only Current Lowest Level Terms
• When to Request a Term
• Use of Medical Judgment in Term Selection
• Selecting More than One Term
• Check the Hierarchy
• Select Terms for All Reported Information, Do Not Add Information
Quality of Source Data

Quality Assurance

- Quality of original information impacts quality of output
- Obtain clarification of data
- Can be optimized by careful design of data collection forms and proper training of staff
- Organizations’ coding guidelines should be consistent with MTS:PTC
- Review of term selection by qualified individuals
- Human oversight of automated coding results
Term Selection Points

- Diagnoses and Provisional Diagnoses with or without Signs and Symptoms
- Death and Other Patient Outcomes
- Suicide and Self-Harm
- Conflicting/Ambiguous/Vague Information
- Combination Terms
- Age vs. Event Specificity
- Body Site vs. Event Specificity
- Location Specific vs. Microorganism Specific Information
- Modification of Pre-existing Conditions
- Exposures During Pregnancy and Breast Feeding
- Congenital Terms
- Neoplasms
- Medical and Surgical Procedures
- Investigations
Term Selection Points (cont)

- Medication/Administration Errors, Accidental Exposures and Occupational Exposures
- Misuse, Abuse and Addiction
- Transmission of Infectious Agent via Product
- Overdose, Toxicity and Poisoning
- Device-related Terms
- Drug Interactions
- No Adverse Effect and “Normal” Terms
- Unexpected Therapeutic Effect
- Modification of Effect
- Social Circumstances
- Medical and Social History
- Indication for Product Use
- Off Label Use
- Product Quality Issues
• Provides data retrieval and presentation options for industry or regulatory purposes

• Objective is to demonstrate how data retrieval options impact the accuracy and consistency of data output

• Most effective when used in conjunction with MedDRA Term Selection: Points to Consider document
General Principles

• Quality of Source Data
• Documentation of Data Retrieval and Presentation Practices
• Do Not Alter MedDRA
• Organization-Specific Data Characteristics
• Characteristics of MedDRA that Impact Data Retrieval and Analysis
• MedDRA Versioning
Do Not Alter MedDRA

• MedDRA is a standardized terminology with a pre-defined term hierarchy

• Users must not make *ad hoc* structural alterations, including changing the primary SOC allocation

• If terms are incorrectly placed, submit a change request to the MSSO
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
Summary

- Introduction to the PTC documents
- Development and maintenance
- How to obtain and use the documents
- Overview of contents

- PTC Working Group welcomes feedback!
MSSO Contacts

• Web site
  – www.meddramsso.com

• E-mail
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