

MedDRA Term Selection:
Points to Consider Document
Presentation to MedDRA Users Group

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November 12, 2003

Development of the Points to Consider (PTC) Document

- ICH-endorsed guide for MedDRA users
- Not an ICH step document
- Developed and maintained by the ICH MedDRA PTC working group (M1 PtC)
 - Regulatory and industry representation
 - U.S., Europe, Japan, Canada, MSSO, JMO

Implementation and Maintenance of PTC

- M1 PtC Workgroup established 1999
- PTC first release: February 2000
- PTC release 3.1: September 2002
 - Availability: ICH, MSSO and regulator websites
- Modifications based on:
 - MedDRA version updates (twice per year)
 - MedDRA user experience based on comments received through MSSO website

MedDRA® TERM SELECTION: POINTS TO CONSIDER

Release 3.1

Based on MedDRA version 5.1

ICH-Endorsed Guide for MedDRA Users

**Application to Adverse Drug Reactions / Adverse Events
&
Medical and Social History & Indications**

12 September 2002

Objective of the PTC

Promote consistency in term selection

- Enhance medical accuracy when retrieving or sharing data
 - within organizations
 - between organizations
 - premarketing and postmarketing
 - worldwide

The PTC does NOT

- Address regulatory requirements
- Address every term selection need
 - medical judgment and common sense needed
- Replace MedDRA training

Importance of PTC Document to FDA (1)

- International reference that promotes MedDRA term selection consistency
 - FDA recommends PTC use to U.S. industry
 - Organizations can develop own procedures which should not be conflicting with PTC

Importance of PTC Document to FDA (2)

- Adverse Event Reporting System (AERS) database receives reports from hundreds of manufacturers
 - no standards → inconsistent adverse event data
 - concerns: retrieval, safety signal identification
 - change from FDA coding of paper reports to manufacturer coding of electronic reports

Examples:
PTC Document Concepts

Choice of Term

- Lowest level that most accurately reflects reporter's words
- If no exact match, use closest term
 - medical judgement
 - request of a new term from MSSO

Do Not Omit Information

- Terms should be selected for all reported medical concepts
- Regardless of perceived relationship
 - do not exclude terms based on causality assessment

Do Not Add Information

- If signs and symptoms are reported, do not create a diagnosis

Example: If abdominal pain, increased serum amylase, and increased serum lipase are reported, it is inappropriate to assign a diagnosis of “pancreatitis”

Points on Diagnoses

- Diagnosis + signs and symptoms
 - select term for diagnosis; optional for signs/symptoms

Example: If “anaphylactic reaction” is reported with rash, dyspnea, hypotension, and laryngospasm, selecting “anaphylactic reaction” alone is appropriate

- Provisional diagnoses
 - such as “rule out”, “possible”
 - treat as if definitive diagnosis

Pre-existing Medical Conditions

- Medical conditions that have not changed
 - can code as medical history
 - do not code as adverse events
- Modified medical conditions
 - such as exacerbated, aggravated, progression
 - if term exists with condition and modifier: use it
 - condition has priority over modifier if term does not exist for the combination
 - halitosis worsened* → halitosis
 - disease+modifier terms now at LLT

Investigations

- Used to capture test names (without qualifiers)
- Used to capture ADRs
 - medical conditions vs. laboratory results
 - separate concepts in MedDRA

Example: If “hypoglycemia” is reported, select

“Hypoglycemia”: “Hypoglycemia” links to the Metabolism and nutrition disorders SOC

Example: If “decreased glucose” is reported, select

“Glucose

decreased”: “Glucose decreased” links to the Investigations SOC

- Terms in Investigations SOC not linked to

Medical/Surgical Procedures

- Can be used to code medical history
- May or may not represent ADRs: use when:
 - procedure represents only information on ADR
Patient had liver transplantation
 - event has priority over procedure when presented as combination term
liver transplantation due to liver failure
 - but can choose terms for both
liver transplantation due to liver failure

Medication Errors/ Accidental Exposures

- Use to capture occurrence of medication error (ME) or accidental exposure (AE)
- May or may not result in ADR
 - if ADR, code closest ME or AE term + ADR term
 - if no ADR, code ME or AE term with or without “no adverse effect” term

Example: If “medication was given intravenously instead of intramuscularly without sequelae” is reported, select “Wrong route of administration” and “No adverse effect”

Social Circumstances

- Can be used to code social / medical history
patient is a cigarette smoker
- May or may not represent ADRs: use when:
 - term from this SOC represents the only option to code the ADR concept
patient abused Drug X → drug abuse
- Social Circumstances SOC not multiaxial

Indications for Product Use

- An area in MedDRA that needs further development
- Types of indication terms
 - medical conditions
 - prevention and prophylaxis
 - diagnostic testing
 - supplementation and replacement therapies
 - procedures
 - “drug use for unknown indication”

Other Key Concepts in PTC

- Death
- Combination terms
- Body site vs. event
- Congenital terms
- Drug interactions
- Modification of effect
- Other

Extension of M1 PtC Remit to Data Output

- Brussels July 2003: proposal to SC
- Initial draft in Osaka November 2003
 - address general principles of data output
- M1 PtC will continue to maintain *Term Selection* document