



Facilitating the Use of MedDRA

**ICH MedDRA Management Board
Special Session, La Hulpe, June 2, 2013**

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Introduction

- **Development of MedDRA represented a significant step forward in harmonisation of adverse event reporting**
 - Available in 11 languages but content is the same (no regional differences)
 - MedDRA responds to the needs of users through change requests
- **Next challenge was to support the consistent use of MedDRA**
 - This support comes in multiple forms

Points to Consider Documents

MedDRA[®] TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.5
Based on MedDRA Version 16.0

1 April 2013

MedDRA[®] DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users
on Data Output

Release 3.5
Based on MedDRA Version 16.0






















1 April 2013

- **Serve as a basis for conventions and SOPs for MedDRA users**
 - Provided as a PDF document, Word document, and online reference
 - Available in English and Japanese
 - Updated with each release of MedDRA by ICH PTC WG

Training

- **Subscribers receive free training and webinars**
 - Face-to-face – MSSO instructor conducts classroom all day training on basic and advanced topics
 - Over 1000 attendees (43 classes) in 2012
 - Webinars – shorter (2 hours maximum) training conducted over the web with an MSSO instructor
 - Capable of providing training in multiple languages
- **Free videocasts available to all**
 - Short (30 minutes maximum) recorded sessions focusing on a single topic
 - Available in multiple languages

MSSO Videocast Training

Videocast Name	Chinese	English	French	German	Spanish
		  And Others			
What's New with MedDRA Version 15.1					
MedDRA Structure and Scope					
Standardised MedDRA Queries (SMQs)					
MedDRA Version Updates					
MedDRA Version Analysis Tool (MVAT)					
Primary System Organ Class (SOC) Allocation in MedDRA					
MedDRA Desktop Browser Research Bin and Export Functions					

Also developing How to Get Started with MedDRA as a new topic

Release Documentation

- **MedDRA release documentation updated with each release of MedDRA**
 - MedDRA Introductory Guide
 - SMQ Introductory Guide
 - What's New document
 - Distribution File Format Document
 - All of these documents are publicly available on MedDRA website
- **Available in 11 languages**
 - Chinese, Czech, Dutch, English, French, German, Hungarian, Italian, Japanese, Portuguese, and Spanish

Best Practice Documents

- **Developed by the MSSO, endorsed by the MedDRA Management Board**
- **To support the harmonisation of MedDRA's use**
 - Primary System Organ Class (SOC) Allocation in MedDRA
 - MedDRA Implementation and Versioning for Clinical Trials
 - Single Case Reporting Using Semi-annual Version Control
 - Implementation of MedDRA Supplemental Terms
- **Available in all MedDRA languages**

Software Tools

- **Several tools are available as part of the subscription**
 - Desktop and Web-based Browsers
 - Browsing and searching MedDRA
 - Versioning tool (MVAT)
 - Identifies impacts of MedDRA changes between any releases
 - Change Request tool (WebCR)
 - Web-based tool to help users submit changes to MedDRA

MedDRA Website



Medical Dictionary for Regulatory Activities

Search the site

Welcome to MedDRA

In the late 1990s, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) developed MedDRA, a rich and highly specific standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans... (more)

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Discover MedDRA

MVAT Tool
Impact of MedDRA versions on your data
1179x1046
[Learn more](#)

MedDRA Training

<p>13 June 2013 EMA, London, UK Coding with MedDRA</p>	<p>14 June 2013 EMA, London, UK MedDRA Safety Data Analysis and SMQs</p>
<p>10 May 2013 Ottawa, Canada MedDRA Safety Data Analysis and SMQs</p>	<p>14 February 2013 Charlottesville, VA USA Intro to MedDRA</p>

Recent News

6 May 2013
Freeze Date Reminder for MedDRA Version 16.1 Change Requests
The last day to submit change requests for Version 16.1 is 1 Jun 2013 at 1700 US EDT. Submit change requests using WebCR.

9 April 2013
Join us for the MedDRA User Group Meeting in Beijing (北京) China
Due to meeting space limitations, registrations will be accepted on a first come, first served basis.

3 April 2013
Join us for the MedDRA User Group Meeting in Boston, MA, USA

- **Source of MedDRA information and guidance**
- **Designed to support new and experienced users**
- **To be launched soon**



Thank You!

International Conference on Harmonisation of Technical Requirements
for Registration of Pharmaceuticals for Human Use