



MedDRA概述、编码规则及使用时的考虑

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ICH药物警戒相关指南研讨会
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MedDRA | Agenda

- Basic of MedDRA use(MedDRA使用的基本信息)
 - When, where, and how MedDRA is used
- Getting started with MedDRA (准备引入/使用 MedDRA)
 - Stakeholders in MedDRA community (MedDRA社会成员)
 - MSSO's roles (MSSO的职责)
 - Implementing MedDRA (引入MedDRA)
 - MedDRA data sharing (MedDRA数据共享)



MedDRA

Agenda (cont)

- MedDRA terminology and MedDRA user Guides (MedDRA 术语和用户指南)
 - Fundamentals of MedDRA terminology (MedDRA 术语基本点)
 - MedDRA maintenance (MedDRA 维护)
 - Download MedDRA (如何下载 MedDRA)
 - ICH Points to Consider (PTC) documents (ICH考虑要点文档)
 - Condensed PTC documents in Chinese (ICH考虑要点文档精要版 - 中文版)
- MSSO Services (MSSO 服务范围)
 - Help Desk (服务台)
 - Training (培训)
 - Tools (软件工具)
 - MedDRA.org website (MedDRA官方网站)

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MedDRA

Basics of MedDRA Use (MedDRA使用的基本信息)

- When, Where, and How MedDRA Is Used



MedDRA

What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities

《监管活动医学词典》



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MedDRA

MedDRA's Purpose

- Facilitate the exchange of clinical information through standardization (通过标准化促进临床信息交流)
- Important tool for product evaluation (评估), monitoring (监测), communication (交流), electronic records exchange (交流), and oversight (监督管理)
- Supports coding (编码) (data entry) and retrieval (检索) and analysis (分析) of clinical information about human medical products including pharmaceuticals (化学药), biologics (生物制品), vaccines (疫苗), and drug-device combination products (药物—器械综合产品)

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MedDRA

When to use MedDRA

MedDRA Definition

- MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry (药监部门和制药业). The terminology is used through the entire regulatory process (整个监管过程中), from pre-marketing to post-marketing, and for data entry (数据输入), retrieval (检索), evaluation (评估), and presentation (展示).

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MedDRA

Where MedDRA is Used



Regulatory Authority and Industry Databases
 Individual Case Safety Reports (ICSR) (个例安全报告) and
 Safety Summaries
 Clinical Study Reports (临床研究报告)
 Investigators' Brochures (临床研究者手册)
 Core Company Safety Information
 Marketing Applications (上市申请)
 Publications
 Prescribing Information (处方信息)
 Advertising

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MedDRA

MedDRA's Scope

- Information included in MedDRA
 - Medical conditions
 - Indications (适应症)
 - Investigations (tests 检查, results 检查结果)
 - Medical and surgical procedures (手术及医疗操作)
 - Medical, social, family history (病史, 家史, 社会史)
 - Medication errors (用药错误)
 - Product quality issues (产品质量问题)
 - Drug-device combination product issues
 - Pharmacogenetic (药物基因学) terms
 - Toxicologic (毒理) issues
 - Standardised MedDRA Queries (标准 MedDRA 分析查询)

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MedDRA

How MedDRA Is Used

- ICH E2B (R3) – Individual Case Safety Report (个例安全报告)

Element ID	E2B(R3) Element Name
B.1.7.1.r.a.2	Structured Medical History Information (disease / surgical procedure / etc.)
B.1.8.rf.2	Indication
B.1.8.r.g.2	Reaction
B.1.8.4.b1	Reported cause(s) of death
B.1.9.4.r.b1	Autopsy-determined cause(s) of death
B.1.10.7.1.r.a.2	Structured information (disease / surgical procedure / etc.) - parent/child report (parent)
B.1.10.8.rf.2	Indication - parent/child report (parent)
B.1.10.8.r.g.2	Reactions (if any and known) - parent/child report (parent)
B.2.i.1.b	Reaction/event in MedDRA terminology
B.3.r.c2	Test Name (MedDRA code)
B.4.k.7.r.2a	Indication in MedDRA terminology
B.5.3.r.2	Sender's diagnosis/syndrome and/or reclassification of reaction/event

Regulatory Database
监管部门数据库



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Getting Started with MedDRA (准备引入/使用MedDRA)



Stakeholders in MedDRA Community (MedDRA社区成员)

- MedDRA community





MedDRA | MSSO's Roles (MSSO 的职责)

- Distribute (颁发) MedDRA: deliver MedDRA to subscribers worldwide
- Maintain (维护) MedDRA: process users' change requests
- Develop (开发) MedDRA: further develop MedDRA to keep up with the changes in medicine and meet the regulatory needs
- Provide (提供) user support
 - Free Help Desk service
 - Free training: face-to-face, webinar, videocast
 - Free user group meetings held in US, Europe, and China, and more...

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MedDRA

ISO Certification (ISO证书)



- MSSO certified as ISO 9001:2015 compliant
 - ISO 9001:2015 standard is an internationally recognized quality management system standard
 - Developed by the International Standards Organization (ISO)
- MSSO has held ISO certifications continuously since 2003
- Involves:
 - Inspection of SoPs
 - Inspection of records to support the use of SoPs
 - Interviews with MSSO staff to ensure understanding of processes

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MedDRA

Implementing MedDRA (引入 MedDRA)

- Establish an implantation team
 - Set goals and objectives
- Have an implementation plan to consider
 - Define roles and responsibilities
 - Who is responsible for getting a MedDRA subscription?
 - Who is responsible for IT?
 - Who is in charge of communication?
 - Who is responsible for data conversion (if applicable)?
 - Identify impacts to your organization's standard operating procedures
 - Plan for staff training: who, when, and what
 - Include IT considerations: database, system, and tools
 - Set implementation timeline

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MedDRA

Obtaining MedDRA Subscription (订阅MedDRA)

- A valid MedDRA subscription is required for any person/organization to use MedDRA
- Step by step instruction on how to apply for MedDRA subscription and pay for MedDRA invoice (commercial organizations) are available in Chinese at: <https://www.meddra.org/chinese-subscription-rates>
 - 如何订阅 MedDRA
 - 如何递交公司年销售额: only for commercial organizations
 - 如何支付 MedDRA 的invoice: only for commercial organizations

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MedDRA

MedDRA Subscription Rates (MedDRA订阅费)

- Enterprise wide subscription (以公司为单位)
- Free subscription (免费订户)
 - Nonprofit organizations (非盈利机构)
 - Regulatory authorities (监管机构)
- Paid subscription (付费订户)
 - Software developers (软件开发公司)
 - Commercial organizations (盈利机构), such as pharma companies, CROs
 - Sliding scale subscription fee based on annual revenue
 - Example, A company with annual revenue (年销售额) less than \$1 million (630万人民币) pays \$162 (1020人民币) per year.

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2018 MedDRA订阅费

- Commercial 0-2 subscription rates reduced in 2018
- Reduction (减价) is a reflection of the continued success of MedDRA as a global standard in public health
- Costs of maintaining and developing MedDRA are distributed over a wider base
 - While still providing the same high standard of tools and services to MedDRA users
 - In fact, expanding services to include more translation and more software tools

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2018 MedDRA订阅费表

MedDRA Subscription Types	2018 Annual Subscription Rates	Additional Rates for Japanese Translation
Regulatory Authority	\$0 USD	\$0 USD
Non-Commercial / Non-Profit	\$0 USD	\$850 USD
Commercial (Parent Company Annual Revenue or Turnover)		
Level 0 (Annual Revenue < \$1 Million)	\$162 USD	\$850 USD
Level 1 (Annual Revenue \$1-\$10 Million)	\$688 USD	\$850 USD
Level 2 (Annual Revenue \$10-\$20 Million)	\$2,627 USD	\$850 USD
Level 3 (Annual Revenue \$20-\$500 Million)	\$4,976 USD	\$850 USD
Level 4 (Annual Revenue \$500 Million-\$1 Billion)	\$10,440 USD	\$850 USD
Level 5 (Annual Revenue \$1-\$5 Billion)	\$43,316 USD	\$850 USD
Level 6 (Annual Revenue \$5-\$20 Billion)	\$57,194 USD	\$850 USD
Level 7 (Annual Revenue > \$20 Billion)	\$74,620 USD	\$850 USD
System Developer	\$2,691 USD	\$850 USD

76% of all MedDRA users pay no fee or \$688 (or less)

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MedDRA

IT Considerations (软件系统)

- Many software tools available to support the use of MedDRA
 - Several provided free with the MedDRA subscription
 - Two browsers (Desktop 桌面浏览器 and Web-Based 网页浏览器)
 - MedDRA Version Analysis Tool (MVAT) 版本分析工具
 - Need for software tools should be driven by the volume of data to be supported (软件类别取决于数据量)
 - With small amounts of data users can use simple software tools (e.g., free MSSO browsers, spreadsheets)
 - Larger implementations should consider commercial data management software products
 - List of third-party software tools on MedDRA website

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MedDRA

IT Considerations(cont)

- At MedDRA.org

Commercial software tools – there are a number of different commercial software tools including submitters, clinical data management systems, and safety systems that have implemented MedDRA.

[Commercial Software Tools](#)

Commercial tools / Tools / How to Use / #

The MedDRA Management Committee and the MSSO contractor make no claims or guarantees regarding the products provided by the vendors listed below. Please contact the vendors directly for more information.

If you have a product that you feel should be listed on this page, please contact the MedDRA MSSO.

Coding and Browsing Tools

- Aik Group, LLC
- Clinical Studio
- GDS Software Solutions, Inc.
- Green Pharmacovigilance software
- Evidus
- Flat Database EDC
- Flat Database PV System
- HARCOM Solutions
- HARCOM Safety Suit 1.0.1
- KMS Network
- Linguistics ICE
- MacroCare HCOODER
- MedCare (Phuderta Group LLC)
- Medidata Solutions Worldwide
- MedInfo, Inc.
- Nuance
- Oracle®
- Pegasus Quality Solutions
- PFD
- Pharis
- Sparta Systems – CAPA Software
- Tamer aCohort®
- Tamer PV System
- Veeva

Tools that support Standardized MedDRA Queries (SMQs)

- Aik Group
- Enginix™ Signal (Oracle)
- Flat Database PV System
- MedCare (Phuderta Group LLC)
- PFD
- Treasure Management System (TMS) (Oracle)

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MedDRA

IT Considerations (cont)

- Build robust MedDRA safety database based on the knowledge of
 - Structure and relations of MedDRA tables
 - Versioning impact
 - Data retrieval needs
- Reference document – MedDRA发布文件格式文档 (MedDRA Distribution File Format Document)
 - Describe the relationships among MedDRA tables.

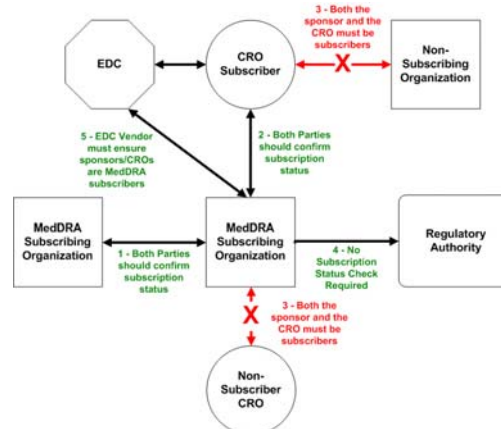
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MedDRA

MedDRA Data Sharing (MedDRA 数据共享)

- MSSO Statement on MedDRA Data Sharing is posted at (MSSO关于 MedDRA数据共享的声明)
<https://www.meddra.org/subscription/process>
- According to MedDRA Subscription Agreement (MedDRA订阅规定)

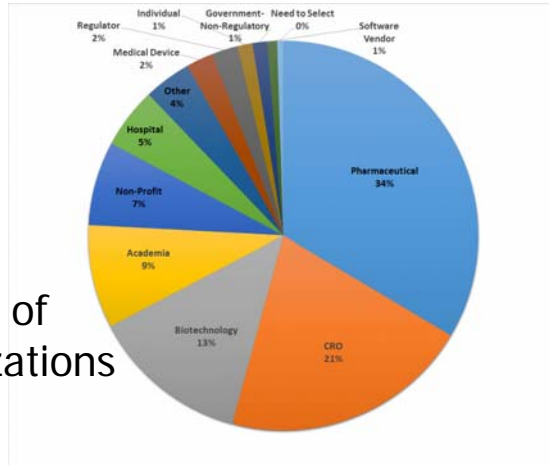


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MedDRA Users Profile (用戶概況)

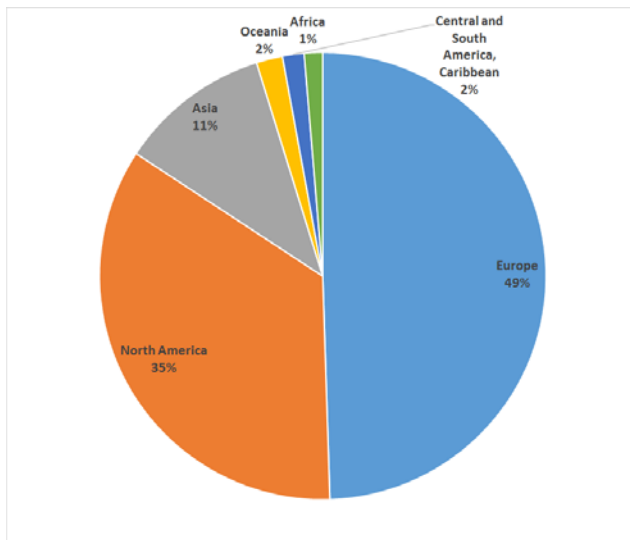
- As of Dec 2017
 - 5,000 Subscribing organizations (MSSO+JMO)
 - 115 Countries
- Graph shows types of subscribing organizations



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MedDRA Users by Region and Top 20 Countries



Country	Count
United States	1439
Germany	331
United Kingdom	322
France	244
Italy	220
China 中国	146
Spain	143
Canada	116
Australia	88
South Korea	84
Poland	83
Switzerland	77
Netherlands	77
Sweden	74
India	70
Belgium	68
Greece	56
Denmark	47
Austria	47
Portugal	42

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MedDRA Terminology and MedDRA User Guides (MedDRA 术语和用户指南)



Fundamentals of MedDRA terminology (MedDRA 术语基本点)

MedDRA Hierarchy (纵向结构)

System Organ Class (SOC) 系统器官分类 (27)



High Level Group Term (HLGT) 高位组语 (337)



High Level Term (HLT) 高位语 (1,738)



Preferred Term (PT) 首选语 (22,499)



Lowest Level Term (LLT) 低位语 (77,248)

MedDRA Version 20.0

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MedDRA

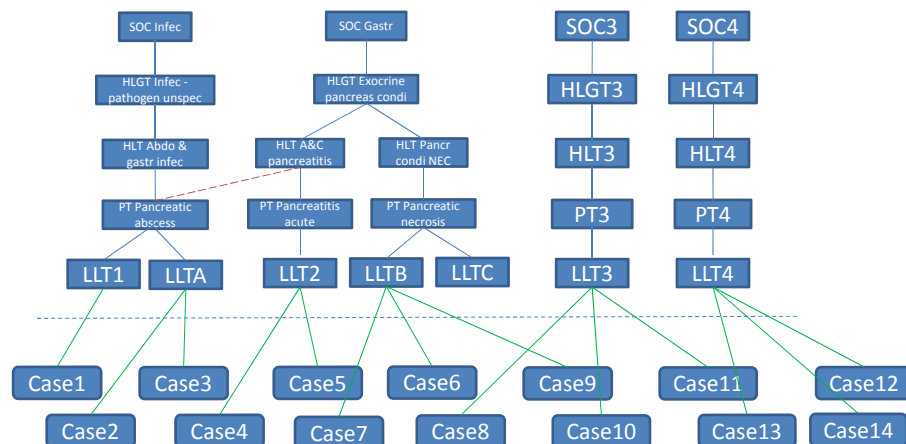
Fundamentals of MedDRA terminology (cont)

MedDRA System Organ Classes (系统器官分类)

- 血液及淋巴系统疾病
- 心脏器官疾病
- 各种先天性家族性遗传性疾病
- 耳及迷路类疾病
- 内分泌系统疾病
- 眼器官疾病
- 胃肠系统疾病
- 全身性疾病及给药部位各种反应
- 肝胆系统疾病
- 免疫系统疾病
- 感染及侵染类疾病
- 各类损伤、中毒及手术并发症
- 各类检查
- 代谢及营养类疾病
- 各种肌肉骨骼及结缔组织疾病
- 良性、恶性及性质不明的肿瘤（包括囊状和息肉状）
- 各类神经系统疾病
- 妊娠期、产褥期及围产期状况
- 产品问题
- 精神病类
- 肾脏及泌尿系统疾病
- 生殖系统及乳腺疾病
- 呼吸系统、胸及纵隔疾病
- 皮肤及皮下组织类疾病
- 社会环境
- 各种手术及医疗操作
- 血管与淋巴管类疾病

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MedDRA and Coded Cases

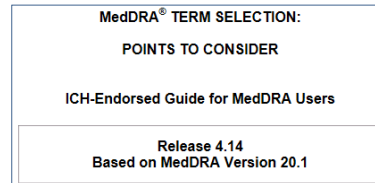


Use MedDRA hierarchy to retrieve cases

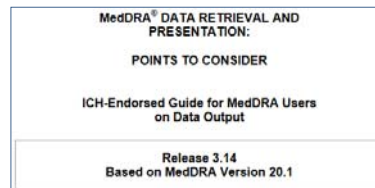


ICH MedDRA User Guides – PTC Documents (ICH考虑要点文档)

- MedDRA Term Selection: Points to Consider (MedDRA术语选择:考虑要点)



- MedDRA Data Retrieval and Presentation: Points to Consider (MedDRA数据检索和展示:考虑要点)



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ICH MedDRA User Guides – PTC Documents (cont)

- Developed by an ICH working group
 - Regulators and industry representatives from ICH regions
 - WHO
 - MSSO and JMO
- Updated twice yearly with each MedDRA release
- Available on MedDRA and JMO websites
 - English and Japanese (只有英文版和日文版)
 - Word (“clean” and “redlined”), PDF, HTML formats
 - “Redlined” document identifies changes made from previous to current release of document

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ICH M1 Points to Consider Working Group (PtC WG)



Meeting 13-15 November 2017, Geneva, Switzerland

- Regulators and industry from EU, US, and Japan
- MFDS, Republic of Korea
- Health Canada, Canada
- MSSO
- JMO

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Condensed PTC Documents in Chinese

- Condensed (精要版) PTC documents are translated into all other MedDRA languages
 - Contain all PTC principles with fewer examples
- Will be available to users in late half of 2018



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MedDRA

PTC Companion Document

- New addition to PTC Document, focus on
 - Data quality
 - Medication errors
- Will be available to users in late half of 2018

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MedDRA

Fundamentals of MedDRA terminology (cont)

- MedDRA languages (MedDRA语言版本)



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MedDRA

MedDRA维护

- MedDRA 是一个根据用户反馈信息进行更新的术语集
 - 用户反馈信息
 - MSSO 积极维护和响应
- 用户可以提交修改申请，由MSSO 进行审核确认
 - MedDRA 变更(英文)
 - MedDRA 中文译文的修改
 - MSSOrequest@meddra.org
 - Each organization: up to 100 CRs per month
 - For simple changes (简单更改要求) (PT and LLT levels), notification of final disposition within 7-10 working days
 - Complex changes (复杂更改要求) above PT level received all year round. Posted for users' comments mid-year.

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MedDRA

MedDRA维护（续）

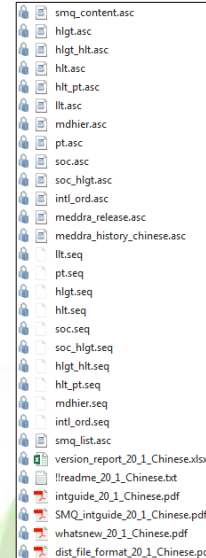
- 每年进行2次正式更新
 - 9月1日发布X.1 英文版（只有简单的变化）
 - 9月15日—MedDRA的翻译版
 - 3月1日发布X.0 英文版（复杂和简单的变化）
 - 3月15日—MedDRA的翻译版

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MedDRA Release Zipped Package (版本文件压缩包)

- Release documents include:
 - MedDRA Introductory Guide* (MedDRA 入门指南)
 - SMQ Introductory Guide* (标准MedDRA 分析查询入门指南)
 - What's New document*
 - Distribution File Format Document* (MedDRA发布文件格式文档)
 - Detail Change Request Report
 - SMQ Spreadsheet
 - Version Report
 - * Translated in all MedDRA languages



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What to do with the Contents of the Zip File (压缩包)?

SMQ电子数据表
标准MedDRA分析
查询入门指南
版本报告
新增内容

MedDRA发布文件
格式文档

MedDRA入门指南

Item	Who should receive it?
MedAscii Directory	IT staff to load MedDRA
SEQAscii Directory	IT staff to review changes
Readme	All users
SMQ Spreadsheet	Those using SMQs
SMQ Introductory Guide	Those using SMQs
Version Report	Those interested in version changes
What's New	All users
Detail Report	Those interested in version changes
Distribution File Format	IT staff to load MedDRA
MedDRA Introductory Guide	All users

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Download MedDRA (如何下载 MedDRA)

Click on Downloads

Learn more about MedDRA in ICH's publications:
 "Understanding MedDRA"
 Factsheet - Multilingual MedDRA
 Factsheet - Accessing MedDRA

Related Links:
 阅读中文MedDRA订购指南

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Download MedDRA (cont)

Log in Request new password

MedDRA ID *
 90001
 Enter your MedDRA ID

Password *

 Enter the password that accompanies your username.

Log in

- Enter Subscriber ID and password

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MedDRA

Download MedDRA (cont)

Downloads

The MSDO download page provides access to the following types of information:

MedDRA Release packages – This includes all of the MedDRA data files and supporting documentation for all versions and supported MedDRA languages for the past six years. Please contact the MSDO Help Desk for any release packages earlier than what is provided above.

MedDRA Desktop Browsers – the MSDO Desktop Browser and the JMD's Desktop Browser are available for download.

- MedDRA Desktop Browsers

MedDRA supplemental releases (in weekly and comprehensive versions) are available for download.

- Supplemental Changes

MedDRA Version Releases:

MedDRA Version 16.1 September 2013

Release package	Language	Size
MedDRA 16.1 中文	Chinese	6.67 MB
MedDRA verze 16.1 Čeština	Czech	6.74 MB
MedDRA Versie 16.1 Nederlands	Dutch	6.23 MB
MedDRA Version 16.1 English	English	6.48 MB
MedDRA Version 16.1 Français	French	6.37 MB
MedDRA Version 16.1 Deutsch	German	6.24 MB
MedDRA 16.1 változat Magyar	Hungarian	6.58 MB
MedDRA versione 16.1 Italiana	Italian	6.17 MB
MedDRA (1-15) 16.1 日本語	Japanese	12.48 MB
MedDRA 16.1 16.1 中国語	Japanese	948.97 KB
MedDRA Versão 16.1 Portuguesa	Portuguese	6.24 MB
Versión 16.1 de MedDRA Español	Spanish	6.3 MB

- Select the version and language(s)
 - Password protected zip file
- Save the zip file to your computer

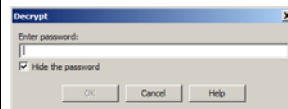
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MedDRA

Extract the MedDRA Files

smq_content.asc
 hlgt.asc
 hlgt_hlt.asc
 hlt.asc
 hlt_pt.asc
 llt.asc
 mdhier.asc
 pt.asc
 soc.asc
 soc_hlgt.asc
 intl_ord.asc
 meddra_release.asc
 meddra_history_chinese.asc
 llt.seq
 pt.seq
 hlgt.seq
 hlt.seq
 soc.seq
 soc_hlgt.seq
 hlgt_hlt.seq
 hlt_pt.seq
 mdhier.seq
 intl_ord.seq
 smq_list.asc
 version_report_20_1_Chinese.xlsx
 treadme_20_1_Chinese.txt
 intguide_20_1_Chinese.pdf
 SMQ_intguide_20_1_Chinese.pdf
 whatsnew_20_1_Chinese.pdf
 dist_file_format_20_1_Chinese.pdf



- Zip file structure and contents
 - Select a file to extract
 - Enter Unzip password from Welcome letter

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MedDRA Transition Date (版本转换日期) (ICSR 个例安全报告)

- A new release version of MedDRA should become the ICSR reporting version on the first Monday of the second month after it is released.
- To synchronize this event over the ICH regions, the MSSO recommends midnight GMT, Sunday to Monday, for the switchover.

- 1 March – MedDRA X.0 released
- First Monday of May – MedDRA X.0 becomes the reporting version
- 1 September – MedDRA X.1 released
- First Monday of November – MedDRA X.1 becomes the reporting version

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MSSO Services (MSSO 服务范围)



MedDRA

Free Help Desk Service (免费服务台)

- MSSO Help Desk: mssohelp@meddra.org
- Hours of operation: 5:00 – 17:00 US Eastern Time.
- Users may ask a variety of questions
 - Subscription
 - Tools
 - Change request
 - Training
 - Meeting

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MedDRA

Free Training (免费培训)

- Formats
 - Face-to-face sessions (课堂培训), webinars (网上培训), videocasts (视频培训)
- Languages
 - English, French, German, Spanish, Mandarin Chinese
- Locations
 - Worldwide and “virtual”

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MedDRA

Free Training (cont)

Face-to-face sessions – Full Day (课堂培训)

- Coding with MedDRA (MedDRA 编码)
- MedDRA: Safety Data Analysis and SMQs (MedDRA: 安全性数据分析和SMQs)
- Getting Started with MedDRA (per request)
- 自2010年，每年在中国办一次
 - 今年九月在上海办培训，具体时间未定

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MedDRA

Free Training (cont)

Webinars – 1 hour (网上培训)

- Introduction module
 - MedDRA Overview
 - Getting Started with MedDRA
- Coding module
 - MedDRA Coding Basics
 - Advanced MedDRA Coding
- Data analysis module
 - Data Analysis and Query Building with MedDRA
 - Standardised MedDRA Queries (SMQs)
- What's New webinar

[YouTube Channel with recorded videocasts and webinars](#)

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MedDRA

Free Training (cont)

- Free videocasts on MedDRA website (视频培训)
 - Short videocasts on a variety of MedDRA-related topics
 - Available in several different languages
 - Can be downloaded or viewed directly on website
 - Available to all

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MedDRA

Free Training (cont)

Videocasts (视频培训)

Videocast Language	Chinese	English	French	German	Spanish
Videocast Topic					
Getting Started with MedDRA	+	+	+	+	+
Introduction to the Points to Consider (PTC) Documents	+	+	+	+	+
MedDRA Structure and Scope	+	+	+	+	+
Standardised MedDRA Queries (SMQs)	+	+	+	+	+
MedDRA Version Updates	+	+	+	+	+
MedDRA Version Analysis Tool (MVAT)		+			
Primary SOC Allocation in MedDRA		+			
MedDRA Desktop Browser 4.0 Enhancements		+			
MedDRA Web-Based Browser (WBB)		+			
Self-Service Application (SSA) Features		+			
The Top 12 Things to Know about the MedDRA Website		+			

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MedDRA

Summary of 2017 Training

- 63 face-to-face sessions (45 subscriber, 18 regulator):
 - 1,736 attendees
 - Central/South and North America, Europe, Asia/Eurasia, Scandinavia
- 27 webinars:
 - 2,705 connections
 - Central/South and North America, Europe, Asia/Eurasia, Africa, Australia, Scandinavia

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MedDRA

Free Tools (免费工具)

- Desktop Browser (MDB) 桌面浏览器
- Web-based Browser (WBB) 网页浏览器
- MedDRA Version Analysis Tool (MVAT) 版本分析工具
- Web-based Change Request Tool (WebCR)
- Self Service Application (SSA) 自助服务工具

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MedDRA

MedDRA.org Website

- Online interface with MedDRA users
- Source of information for
 - Subscribing to MedDRA: 订阅MedDRA
 - Renewing subscription: 续约MedDRA执照
 - Downloading MedDRA: 下载 MedDRA
 - News and Events: 新闻和活动通知
 - MedDRA activities, such as training, meetings
 - Access MSSO tools: MedDRA 工具
 - Points to Consider documents: 考虑要点文档
 - MSSO Best Practice documents: 最佳规范文档
 - MSSO training materials: 培训文档
 - Recorded webinars and videocasts: 录的网上培训课程和视频培训
 - Frequent asked questions (FAQs): 经常问的问题

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MedDRA

Translations of MedDRA

- Your MedDRA subscription includes the following languages
 - English, Chinese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese, Spanish
- MedDRA Japanese translation requires an additional fee.

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Chinese MedDRA WeChat Group (MedDRA群)

- Set up and run by users in China
- Have a few hundred members
- Provide platform to ask questions about MedDRA subscription, coding, data sharing, etc.
- Free to participate
- MSSO is a member of the group
- Contact me if you are interested in joining the group: 若想加入，请与我联系

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Paying Subscription by Credit Card 信用卡付订阅费

- New feature coming later in 2018
- For Level 0-2 commercial subscribers
- Goal is to make paying MedDRA subscription easier for lower revenue users 方便用户

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MedDRA

MSSO Contacts

- Website
 - www.meddra.org
- Email
 - msohelp@meddra.org
- Frequently Asked Questions
 - www.meddra.org/faq

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MedDRA

Medical Dictionary
for Regulatory Activities

Questions?

