



MedDRA

Getting Started with MedDRA



harmonisation for better health



MedDRA

MedDRA was developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Committee, which is composed of the ICH parties, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).

000560

2





MedDRA

Disclaimer and Copyright Notice

- This presentation is protected by copyright and may, with the exception of the MedDRA and ICH logos, be used, reproduced, incorporated into other works, adapted, modified, translated or distributed under a public license provided that ICH's copyright in the presentation is acknowledged at all times. In case of any adaption, modification or translation of the presentation, reasonable steps must be taken to clearly label, demarcate or otherwise identify that changes were made to or based on the original presentation. Any impression that the adaption, modification or translation of the original presentation is endorsed or sponsored by the ICH must be avoided.
- The presentation is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original presentation be liable for any claim, damages or other liability arising from the use of the presentation.
- The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.

000560

3



MedDRA

Course Overview

- Describe what MedDRA is and who uses it
- Describe the process for subscribing to MedDRA
- Discuss development of a MedDRA implementation strategy within your organization
- Provide an overview of tools, services, and training offered as part of a MedDRA subscription
- Discuss the importance of a versioning strategy
- Conclude with a question and answer session

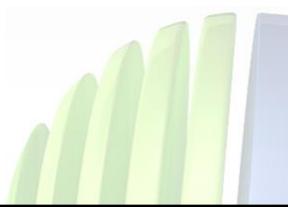
000560

4



MedDRA

MedDRA Description



MedDRA

What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities



MedDRA

MedDRA Definition

MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.

000560



MedDRA

MedDRA's Purpose

- Facilitate the exchange of clinical information through standardization
- Important tool for product evaluation, monitoring, communication, electronic records exchange, and oversight
- Supports coding (data entry) and retrieval and analysis of clinical information about human medical products including pharmaceuticals, biologics, vaccines, and drug-device combination products

000560





MedDRA

MedDRA and the MSSO

- International support and development of terminology
- Foster use of MedDRA through communications and educational offerings
- “Custodians”, not owners, of the terminology
- JMO (partner organization for Japanese-language MedDRA)
- Governed by a Management Committee (industry, regulators, multi-national, other interested parties)

000560

9



MedDRA

Where MedDRA is Used



Regulatory Authority and Industry Databases
Individual Case Safety Reports and Safety Summaries

Clinical Study Reports

Investigators' Brochures

Core Company Safety Information

Marketing Applications

Publications

Prescribing Information

Advertising

000560

10

 **Codes and Languages**

000560

10019211

Electronic Submission

11

Kopfschmerz German	Fejfájás Hungarian
Cefaleia Portuguese	Cefalea Italian
Hoofdpijn Dutch	頭痛 Japanese
Headache English	Cefalea Spanish
Céphalée French	Головная боль Russian
Bolest hlavy Czech	두통 Korean
头痛 Chinese	Cefaleia Brazilian Portuguese



 **Electronic Transmission of Data**

 INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH E2B Expert Working Group

Implementation Guide for
Electronic Transmission of Individual Case Safety Reports
(ICSRs)

E2B(R3) Data Elements and Message Specification

Version 5.01, 12 April 2013

000560

12



MedDRA

Who Uses MedDRA?



MedDRA

Where is MedDRA Used?



MedDRA is in 127 countries

000560

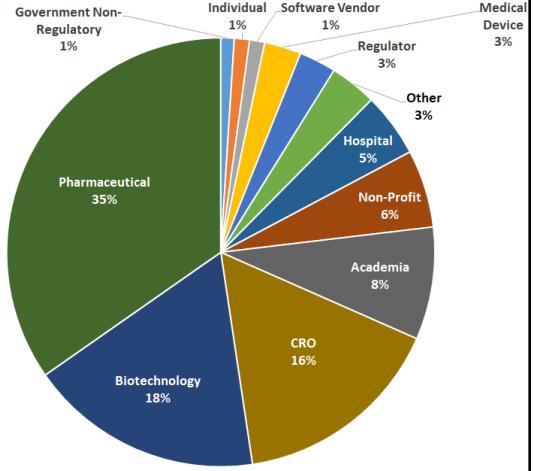
14





MedDRA Users Profile

- As of Dec 2020
 - 6,800 Subscribing organizations (MSSO+JMO)
 - 127 Countries
- Graph shows types of subscribing organizations



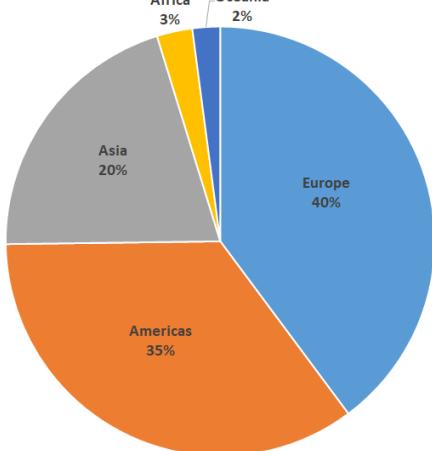
Organization Type	Percentage
Pharmaceutical	35%
Biotechnology	18%
CRO	16%
Academia	8%
Non-Profit	6%
Hospital	5%
Other	3%
Regulator	3%
Medical Device	3%
Software Vendor	1%
Government Non-Regulatory	1%
Individual	1%

000560

15



MedDRA Users by Region



Region	Percentage
Europe	40%
Americas	35%
Asia	20%
Africa	3%
Oceania	2%

Country	Count
United States	1769
China	629
Germany	345
United Kingdom	338
France	258
Italy	211
Republic of Korea	189
Spain	158
Canada	145
India	121
Australia	113
Netherlands	109
Switzerland	104
Egypt	97
Sweden	97
Chinese Taipei	82
Russian Federation	81
Poland	76
Belgium	65
Denmark	59
Israel	58
Greece	57
Portugal	54
Brazil	53
Ireland	51

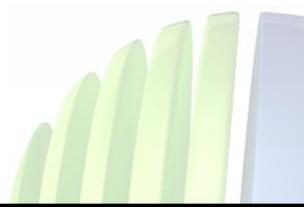
000560

16



MedDRA

Subscribing to MedDRA



MedDRA

MedDRA Subscriptions

- To use MedDRA, you must obtain a subscription
- MedDRA subscriptions are enterprise subscriptions
 - All parts of the organization can use the same subscription
 - No limit to the number of users within an organization
- Subscription grants access to MedDRA for one year
- There are four types of MedDRA subscriptions
 - Regulatory
 - Non-Profit/Non-Commercial
 - Commercial
 - System Developers

000560

18





MedDRA

Types of MedDRA Subscriptions

- Regulatory Authority
 - Eligible to receive MedDRA at no charge
- Non-Profit/Non-Commercial
 - Eligible to receive MedDRA at no charge
 - Non-profit medical libraries, educational institutions, and direct patient care providers (i.e., hospitals for educational use)
 - In general, any organization conducting non-commercial work
- Commercial
 - Commercial organizations (e.g., pharmaceutical companies, CROs)
 - Rates vary based on the annual revenue (turnover) of the organization
- System Developers
 - Reserved for organizations that develop software products that use MedDRA
 - Use is limited to software development and MedDRA testing, not for providing MedDRA support services (e.g., coding, analysis, transmission of MedDRA coded data)

000560

19



MedDRA

What Do I Get with a MedDRA Subscription?



- Access to MedDRA release files
- Full features of MedDRA website
- Submit requests for changes to MedDRA
- Free training
- Help Desk
 - Global support via phone, email, online chat, social media
- Software tools
- MedDRA User Group participation

000560

20



MedDRA

MedDRA 2021 Subscription Rates

MedDRA Subscription Types	2021 Annual Subscription Rates
Regulatory Authority	\$0 USD
Non-Commercial / Non-Profit	\$0 USD
Commercial (Parent Company Annual Revenue or Turnover)	
Level 0 (Annual Revenue < \$1 Million)	\$154 USD
Level 1 (Annual Revenue \$1-\$10 Million)	\$654 USD
Level 2 (Annual Revenue \$10-\$20 Million)	\$2,496 USD
Level 3 (Annual Revenue \$20-\$500 Million)	\$4,727 USD
Level 4 (Annual Revenue \$500 Million-\$1 Billion)	\$9,918 USD
Level 5 (Annual Revenue \$1-\$5 Billion)	\$41,150 USD
Level 6 (Annual Revenue \$5-\$20 Billion)	\$54,334 USD
Level 7 (Annual Revenue > \$20 Billion)	\$70,889 USD
System Developer	\$2,556 USD

000560



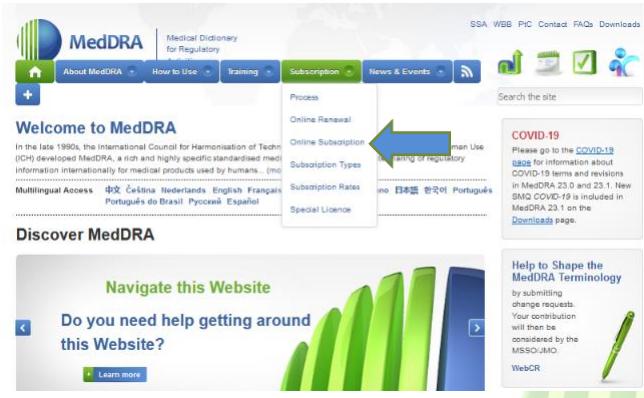
21



MedDRA

Subscription Process

1. Go to MedDRA website (www.meddra.org)
2. Under Subscription, click on Online Subscription





000560



22



MedDRA Subscription Process (cont)

3. Enter Organization Name
4. Select Organization Type
5. Select Subscription Type

The screenshot shows the 'Online Subscription' page. In the 'Organization' section, 'MYPHARMA' is entered. In the 'Subscription Types' section, the 'Commercial' radio button is selected. In the 'Organisation Type' dropdown, 'Pharmaceutical' is chosen. The 'Commercial' option is highlighted with a blue arrow.



Subscription Process (cont)

6. For all subscription types (except regulatory), MSSO requests documentation of organization type and annual revenue (if applicable)
 - User can attach a file or provide a web link for this information

The screenshot shows a form for attaching documentation. It includes a 'No file selected' button, a 'Browse' button, and a text input field with the URL 'www.myfinancialinfo.com'. Below the input field is a placeholder 'Or paste a link to the appropriate web page'. There are also 'Add another PDF' and 'Add another link' buttons.

000560

24



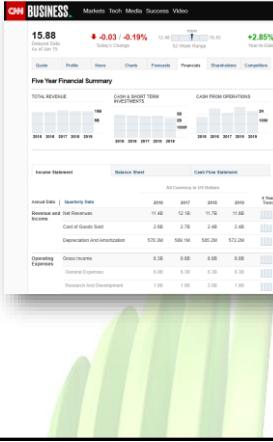
**Commercial License
Financial Information**

www



Letterhead

Or



www

• English

• USD

Signed

PDF



Subscription Process (cont)

26

7. Provide at least one Point of Contact (POC) for your organization

- Many users have a primary POC and a billing POC (who receives MSSO invoices)

Contact Information

Contact Type: *

Contact details

First Name: * Last Name: *

Email: * Confirm Email: *

Add another Contact +

Terms and Conditions

→ Read Terms & Conditions I agree with Terms & Conditions

Submitting your Application Form

Next

000560



MedDRA

Subscription Process (cont)

8. All subscribers must review and agree to subscription Terms & Conditions (which protects MedDRA intellectual property)

→ [Read Terms & Conditions](#) I agree with Terms & Conditions

1. This is a one year subscription, between Northrop Grumman International Trading Inc., incorporated in the State of Delaware, and the Subscriber to MedDRA, commencing twelve (12) calendar months following the enrollment date. The subscription will automatically renew for subsequent periods of one year each from the enrollment anniversary, unless either party gives the other notice of non-renewal at least sixty (60) calendar days before the end of any subsequent subscription term. Notwithstanding the foregoing, Northrop Grumman shall be entitled to give notice of non-renewal if renewal is prohibited by U.S. export law, subscriber is in breach of Subscription Agreement or for commercially reasonable reasons. The MedDRA subscription is available for use by the subscribing organization and any wholly-owned subsidiaries of the subscribing organization, provided the subscription can be made available to and used by such subscribing organization and wholly-owned subsidiaries in accordance with U.S. and any other applicable export control and/or sanctions laws and regulations. All prices shall remain unchanged during the initial subscription period. After the initial subscription period, Northrop Grumman will invite the Subscribers to the then current available subscription for re-negotiation.

[Print](#)

000560

27



MedDRA

Subscription Process (cont)

9. MSSO reviews application and subscription level justification (e.g., commercial organizations may provide an annual report showing revenues)
10. Commercial or developer subscribers receive invoice

MedDRA

MSSO Invoice

MYPHARMA
Billing PoC

Invoice Date: 19 January 2013
Invoice #:
Purchase Order:

Annual MedDRA Subscription (Commercial Level)

Subscription Rate:	\$4,727.00
Sub Total:	\$4,727.00
Invoice Total:	\$4,727.00

Wire Payment Instructions
Please reference Northrop Grumman Sales Number 21280112242 on payment.

Payment Terms: Due upon receipt.

Payment Method: Payment must be made in US Dollars. Checks and wire transfers are accepted forms of payment. Please make checks payable to Northrop Grumman International Trading Inc. and wire transfers must include an ABA bank routing and account number.

REMIT WIRE PAYMENTS TO:
Northrop Grumman International Trading Inc.
MSB# 2710
CMA# 1000000007 - 700
United States
Bank ABA # 312000220
FOR CHECK PAYMENTS:
Northrop Grumman International Trading Inc.
P.O. Box 2770
CMA# 1000000007 East
Linden Lane, Box 2770
Bethesda, MD 20814

FOR INTERNATIONAL CUSTOMERS:
Please reference ref code CHASEUS

000560

28



MedDRA

Payment Methods

- For commercial users, payment is required before access is provided to MedDRA.
- For Commercial 0-2 and Developers, MSSO accepts credit card payments

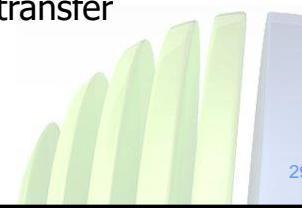


- Organizations can also pay by bank transfer



000560

29



MedDRA

Subscription Process (cont)

11. All new subscribers receive a Welcome Letter that provides MedDRA access instructions

meddra@meddra.org
Mon 1/18/2021 10:01 AM
Cc: medra.domain@feuc.com.br
To: medra.domain@feuc.com.br
Subject: MSSO Help - Welcome to MedDRA
18 January 2021

Dear [REDACTED]

Welcome to MedDRA. Your MedDRA 0-2 subscription period is from 01 February, 2021 to 31 January, 2022. To access MedDRA 0-2 and to receive MedDRA you will need your MedDRA ID and Password which can be retrieved by accessing MSSO's Self Service Application <https://www.meddra.org/meddra-self-service>. The videocast is titled 'Self Service Application Features' <https://www.meddra.org/video-casts>. The videocast is titled 'Self Service Application Features' <https://www.meddra.org/video-casts>.

If you need help with the Self Service Application, the MSSO produced a videocast demonstrating its features. The videocast is titled 'Self Service Application Features' <https://www.meddra.org/video-casts>. The videocast is titled 'Self Service Application Features' <https://www.meddra.org/video-casts>.

After retrieving your credentials, you may access the following services:

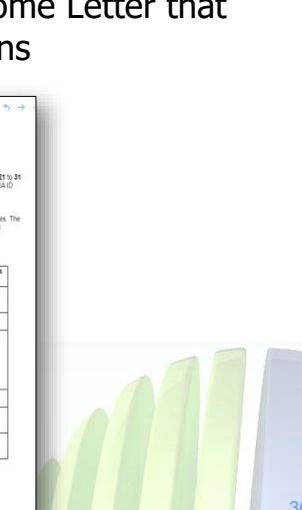
MSSO Service	Related MSSO Web Page	Required Credentials
Access to MedDRA release package	To download and extract files from the zip file at https://www.meddra.org/page/%2fsoftware	MedDRA ID, Password, Unzip Password
Access to WebDR	To submit MedDRA and SDU change requests https://www.meddra.org/page/%2fsubmit	MedDRA ID, Password, CPO
Access to other MedDRA Tools	To access MedDRA Web-Based Browser (WBB) https://www.meddra.org/page/%2fwbb To access MedDRA Data Analysis Tools (MDAT) https://www.meddra.org/page/%2fmdat To register for MedDRA Training https://www.meddra.org/page/%2ftrain	MedDRA ID, Password
Register for MedDRA Training	To register face-to-face Training and webinars https://www.meddra.org/page/%2ftrain	MedDRA ID
Register for MedDRA User Group Meeting	To register MSSO MedDRA User Group Meetings in the United States, Europe, and China https://www.meddra.org/page/%2fgroup	MedDRA ID
Access to MedDRA training materials and videos	To download training materials and to view MSSO video https://www.meddra.org/page/%2ftrain	No credential required

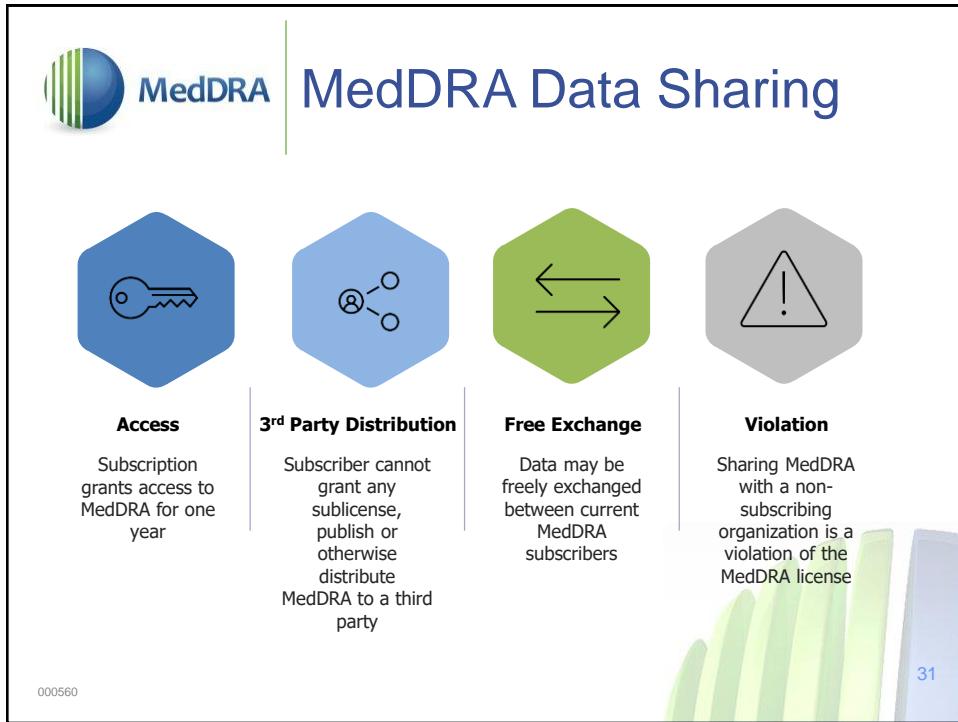
Please feel free to contact the MSSO Help at meddra@meddra.org if we could be of further assistance.

Sincerely,

000560

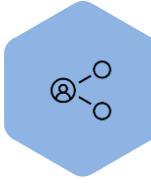
30

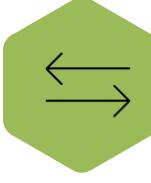




MedDRA Data Sharing

Access  Subscription grants access to MedDRA for one year

3rd Party Distribution  Subscriber cannot grant any sublicense, publish or otherwise distribute MedDRA to a third party

Free Exchange  Data may be freely exchanged between current MedDRA subscribers

Violation  Sharing MedDRA with a non-subscribing organization is a violation of the MedDRA license

000560 31



MedDRA Data Sharing (cont)

- For details, see the Statement on MedDRA Data Sharing

Process / Subscription / 

Under the governance of the ICH MedDRA Management Committee, MedDRA is continuously enhanced to meet the evolving needs of all its users around the world. Sustainability of a high quality terminology needs an income stream and the ICH MedDRA Management Committee has opted for a licensing model that provides access to the terminology free of charge to regulatory authority, non-profit, direct patient care provider, educational institutes and at a fair cost shared by its commercial users through an annual subscription fee.

Here's how to subscribe to MedDRA:

- If your organization is headquartered in Japan, please contact the Japanese Maintenance Organization at <https://www.pmrj.jp/jmohp/index.php>, otherwise continue to Step 2.
- Determine the type of subscription applicable for your organization.
- Determine the rate that is applicable for the subscription type.
- Complete the online subscription form.
- If you are requesting a commercial subscription, please upload an annual report or a signed statement from your organization on letterhead describing total revenue or turnover for its most recently completed fiscal year.
- Your subscription includes English, Chinese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese, and Spanish. If you wish to purchase MedDRA in Japanese, please select Japanese under Additional Language at the bottom of the online subscription form page.
- Submit your online subscription form.
- You may save or print a copy of the completed subscription form after submission.
- The MSSO will email an invoice to the designated billing point of contact for payment if applicable. Upon receipt of payment, the MSSO will provide the information to download MedDRA.

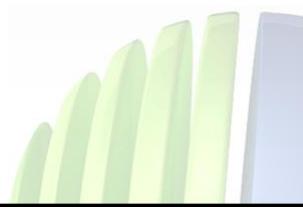
For subscription renewals complete the online renewal form.

000560 32



MedDRA

MedDRA Implementation Strategy



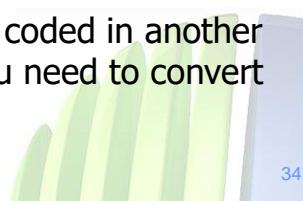
MedDRA

Next Steps

- Once you have subscribed to MedDRA, what's next?
 - Develop your organizational implementation strategy
 - Download the latest MedDRA release
 - Access and use one of the MedDRA browser tools to begin coding and data analysis activities
 - Consider if you already have data coded in another terminology (legacy data) that you need to convert to MedDRA

000560

34





MedDRA

Legacy Data Conversion

- WHO Uppsala Monitoring Centre and the MSSO maintain a WHO-ART to MedDRA bridge to support the conversion of WHO-ART coded data to MedDRA

	A	B	C	D	E	F
1	WHO-ART PT	Adverse reaction record number	MedDRA LLT	MedDRA LLT code	MedDRA PT	MedDRA PT code
2	Abdominal cramps	1011	Abdominal cramps	10000045	Abdominal distension	10000040
3	Abdominal adhesions	1559	Abdominal adhesions	10000050	Abdominal adhesions	10000050
4	Abdominal pain	1068	Abdominal pain	10000081	Abdominal pain	10000081
5	Abdominal rigidity	1874	Abdominal rigidity	10000090	Abdominal rigidity	10000090
6	Abnormal behaviour	2367	Abnormal behaviour	10061422	Abnormal behaviour	10061422
7	Abnormal palmar/plantar creases	1033	Abnormal palmar/plantar creases	10000162	Abnormal palmar/plantar creases	10000162
8	Abortion	1034	Abortion	10000230	Abortion	10000230
9	Abortion missed	1035	Abortion missed	10000230	Abortion missed	10000230
10	Abortion threatened	1236	Abortion threatened	10000242	Abortion threatened	10000242
11	Abrasion NOS	1708	Abrasion NOS	10000245	Excoriation	10049796
12	Absences	1208	Absence seizure	10000331	Petit mal epilepsy	10034759
13	Accident	1087	Accident	10000369	Accident	10000369
14	Acanthosis	1952	Acanthosis	10000349	Acanthosis	10000349
15	Accident NOS	1952	Accident NOS	10000377	Accident	10000369
16	Accidental drug intake by child	2276	Accidental drug intake by child	10064368	Accidental exposure to product by child	10073318
17	Accommodation abnormal	0202	Accommodation abnormal	10000385	Accommodation disorder	10000389
18	Achaliasia cardiae	1152	Achaliasia cardiae	10000422	Esophageal achaliasia	10000336
19	Acid-base balance disorder mixed	1238	Acid-base balance disorder mixed	10000483	Acid-base balance disorder mixed	10000483
20	Acidosis	0363	Acidosis	10000486	Acidosis	10000486
21	Acidosis lactic	0364	Acidosis lactic	10000491	Lactic acidosis	10023676
22	Acidosis metabolic neonatal	2343	Late metabolic acidosis of newborn	10024004	Late metabolic acidosis of newborn	10024004
23	Acidosis respiratory	1465	Acidosis respiratory	10000495	Respiratory acidosis	10038661
24	Acne	0001	Acne	10000496	Acne	10000496
25	Acrodermatitis	1455	Acrodermatitis	10000593	Dermatitis	10012431

000560

35



MedDRA

Organizational Implementation Strategy

- No single method for all organizations
- Implementation approach depends on factors such as size of organization
- MSSO provides many tools and resources to assist implementation

000560

36



MedDRA

Procedures Documentation

- Documentation of procedures and processes is a best practice for all organizations
 - This includes the use of MedDRA
- Standard operating procedures and other relevant documents in an organization should address the use of MedDRA
 - Coding, dictionary management, MedDRA versioning, analytical processes and the use of MedDRA tools

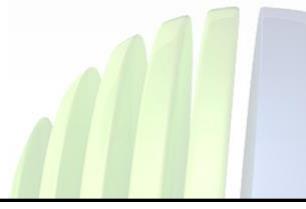
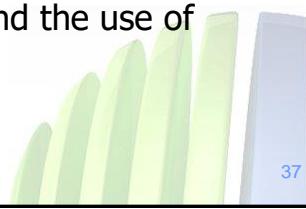
000560

37



MedDRA

Downloading MedDRA Release Files





MedDRA

Downloading MedDRA Release Files



- There is an instructional video describing the process for downloading MedDRA release files on the MedDRA website (www.meddra.org)

<https://www.meddra.org/instructional-videos>

- This video can be streamed in English, Chinese, French, Korean, and Spanish

000560

39



MedDRA

Accessing the MedDRA Browsers





MSSO's MedDRA Browsers



MedDRA Desktop Browser (MDB)
Download MDB and release files from MedDRA website



Mobile MedDRA Browser
<https://mmb.meddra.org>



MSSO's MedDRA Browsers (cont)

- **Features**
 - Each require MedDRA ID and password
 - View/search MedDRA and SMQs
 - Support for all MedDRA languages
 - Language specific interface
 - Ability to export search results and Research Bin to local file system (MDB and WBB only)

 **MedDRA** | **Web-Based Browser**

MedDRA Browser x https://tools.meddra.org/wbb/main_wbb.aspx?nc=Y&inactive=Y&term= covid-19 90% ... Search

Preferred Language: English MedDRA Concept Descriptions, Legends, Alloids Search History New Browser Window MedDRA Documentation User Guide SMQ Analysis, Hierarchical Analysis Logout

Language and Version Options: English English English 24.0 Browser View SOC Restore Default Display Options Show Codes Show Non-Current LLTs

Term: Infections and infestations, Viral infectious disorders, COVID-19

Search Options: SOC: HLT, PT, LLT, Use SOC, Ignore Diacritical Marks, Show PT/LT with categories

Search Results: Total Search Results: 60 Details: PT (10) LLT (50)

PT (LLT): Exact Match - 1, Lexical Variant - 0, Synonym Search Results - 0, Other Search Results - 9, PT Asymptomatic COVID-19, PT Congenital COVID-19, PT COVID-19 immunisation, PT COVID-19 pneumonia, PT COVID-19 prophylaxis, PT COVID-19 screening, PT COVID-19 symptom, PT Post-acute COVID-19 syndrome, PT Suspected COVID-19

Select SOC(s) to Search (default is all SOC(s)): Blood and lymphatic system disorders, Cardiac disorders, Congenital, familial and genetic disorders, Ear, nose, mouth disorders, Endocrine disorders, Eye disorders, Gastrointestinal disorders, General disorders and administration site conditions

Term Details in Primary Language: PT - Preferred Term, MedDRA Code/MedDRA Term: 10084268 COVID-19, SOC Code: 10021981 Infections and infestations, 10038738 Respiratory, thoracic and mediastinal disorders

SMQ Code SMQ Name Scope Status Category Weight 20000237 COVID-19 Narrow Active A 0 Infective

000560 43

 **Installing the MedDRA Desktop Browser**



- There is an instructional video describing how to download the MedDRA Desktop Browser (MDB) and import release files into the MDB on the "Tools" section of the MedDRA Training Materials page on the website (www.meddra.org)

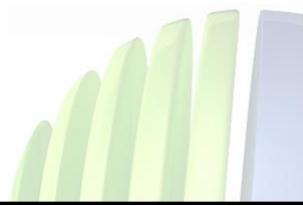
<https://www.meddra.org/training-materials>

- This video can be streamed in English, Chinese, French, German, Korean, and Spanish

000560 44



Overview of MedDRA Tools and Services



MedDRA

Information Technology Resources

- Software tools support the use of MedDRA
 - Several are free with MedDRA subscription
 - MedDRA browsers (Desktop, Web-Based and Mobile)
 - MedDRA Version Analysis Tool (MVAT)
 - Software tools need driven by the volume of data
 - With small amounts, users can use simple software tools (e.g., free MSSO browsers, spreadsheets)
 - Larger implementations may need commercial data management products
 - List of third-party software tools on MedDRA website




MedDRA

Resources at www.meddra.org



- Help Desk
- Subscriptions
- News and Events
- MedDRA user documentation
- MedDRA Best Practices document
- Points to Consider documents
- Terminology downloads
- Training
- Tools
- MedDRA publications
- User Group meetings
- Expert meetings

47


MedDRA

Need for Conventions When Using MedDRA

- Conventions are written guides and sets of principles for using MedDRA that help users achieve consistency in coding and data retrieval
- Conventions also harmonize exchange of MedDRA coded data worldwide
- MedDRA may appear complicated but its structure is logical
- Several guides (Points to Consider documents) are provided to optimize your use of MedDRA

48


MedDRA

Points to Consider (PtC) Documents

PtC Category	PtC Document	Purpose	Languages	Release Cycle
Term Selection	MedDRA Term Selection: Points to Consider	Promote accurate and consistent coding with MedDRA	English, Japanese, Chinese, Korean, and Spanish	Updated annually with the March release of MedDRA
	MedDRA Term Selection: Points to Consider Condensed Version	Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except English, Japanese, and other languages with an available translation of the full MTS:PTC document)	Update as needed
Data Retrieval and Presentation	MedDRA Data Retrieval and Presentation: Points to Consider	Demonstrate how data retrieval options impact the accuracy and consistency of data output	English, Japanese, Chinese, Korean, and Spanish	Updated annually with the March release of MedDRA
	MedDRA Data Retrieval and Presentation: Points to Consider Condensed Version	Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except English, Japanese, and other languages with an available translation of the full DRP:PTC document)	Update as needed

000560 49


MedDRA

Points to Consider (PtC) Documents (cont)

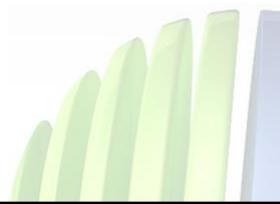
PtC Category	PtC Document	Purpose	Languages	Release Cycle
General	MedDRA Points to Consider Companion Document	More detailed information, examples, and guidance on specific topics of regulatory importance. Intended as a "living" document with updates based on users' needs. First edition covered data quality and medication errors. Updated in July 2020 (Release 1.1). Release 2.0 in October 2020 included new section on product quality issues. Another new section on manufacturing product quality issues is being drafted.	English and Japanese	Updated as needed

000560 50



MedDRA

MedDRA Training



MedDRA

MedDRA Training Opportunities for Users

Free Face-to-Face (F2F) training



- Coding with MedDRA
- Safety Data Analysis and Standardised MedDRA Queries
- Getting Started with MedDRA

Free webinars



- Getting Started with MedDRA
- What is MedDRA and How is It Used?
- MedDRA Coding Basics
- Advanced MedDRA Coding

000560

52





MedDRA

MedDRA Training Opportunities for Users (cont)

- Free webinars
 - Data Analysis and Query Building with MedDRA
 - Standardised MedDRA Queries
 - Let's Code Together
 - MVAT Demonstration
 - Requesting Changes to MedDRA
 - What's New with MedDRA (with each MedDRA release)

000560

53



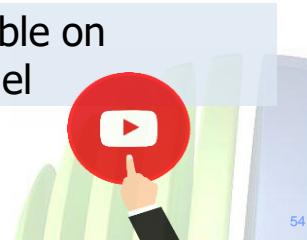
MedDRA

MedDRA Training Opportunities – Available to All (cont)

- Free resources on MedDRA website
 - Slides for all F2F courses and webinars
 - Short videocasts on MedDRA-related topics
 - Available in several languages
 - Can be downloaded or viewed directly on website
 - Help trainees prepare for F2F courses
- Webinars and videocasts available on MedDRA MSSO YouTube Channel

000560

54





MedDRA

MedDRA Versioning



MedDRA

A Question You Might Be Asking



“I already have an old version of MedDRA.
Why do I need to keep subscribing every year?”

000560

56





MedDRA

Reasons to Update to a New MedDRA Version

- MedDRA is updated twice a year in March and September
- Take advantage of new terms and other improvements
- Use the same new version to summarize data from different sources that had used older versions
 - “Pooling” clinical trials for analysis
 - Post-marketing safety summaries, etc.
- Use of recent versions of MedDRA may be required or preferred by regulatory authorities

000560

57



MedDRA

Reasons to Update to a New MedDRA Version (cont)

- Stay current with development partners and contract research organizations
- Harmonize use of MedDRA to optimize communication of data

000560

58



MedDRA

Resources for Version Updates

- MedDRA Best Practices document
- Appendix 4.1 Versioning in the MedDRA Term Selection: Points to Consider document
- MSSO videocast – MedDRA Version Updates
- What's New document
- MSSO "What's New" webinars
- MedDRA Version Reports
- MedDRA Version Analysis Tool (MVAT)

000560

59



MedDRA

Course Summary

In this course, we:

- Described MedDRA and who uses it
- Described the process for subscribing to MedDRA
- Discussed MedDRA implementation topics
- Described tools, services, and training offered with a MedDRA subscription
- Discussed the reasons for a MedDRA versioning strategy

000560

60



MedDRA

MSSO Contacts

- Website
 - www.meddra.org
- Email
 - mssohelp@meddra.org
- Frequently Asked Questions
 - www.meddra.org/faq
- MedDRA Browsers
 - <https://www.meddra.org/meddra-desktop-browsers> (Desktop Browser)
 - <https://tools.meddra.org/wbb/> (Web-Based Browser)
 - <https://mmb.meddra.org> (Mobile Browser)

000560

61



MedDRA

MSSO Contacts (cont)

- Change Request Submission
 - <https://www.meddra.org/how-to-use/change-requests>
- MedDRA Support Documentation
 - <https://www.meddra.org/how-to-use/support-documentation>

000560

62



MedDRA

Question and Answer Session

000560

