Getting Started with 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).

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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

MedDRA

MedDRA Description

MedDRA

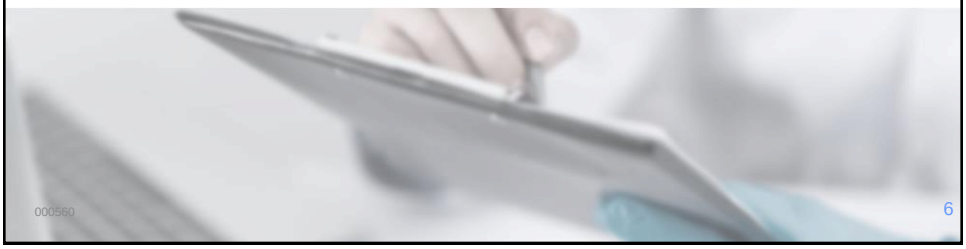
What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities



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.

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

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)

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

Codes and Languages

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

MedDRA

Who Uses MedDRA?

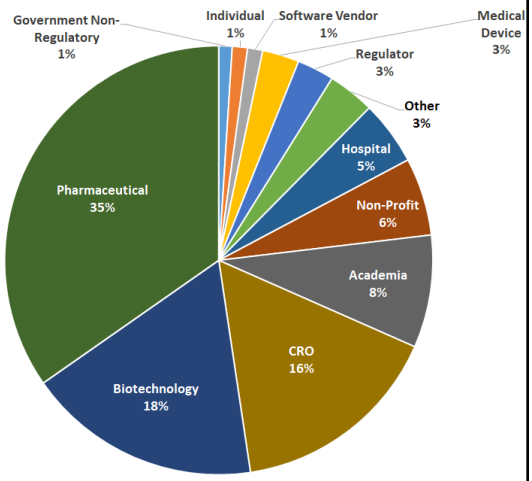
MedDRA

Where is MedDRA Used?

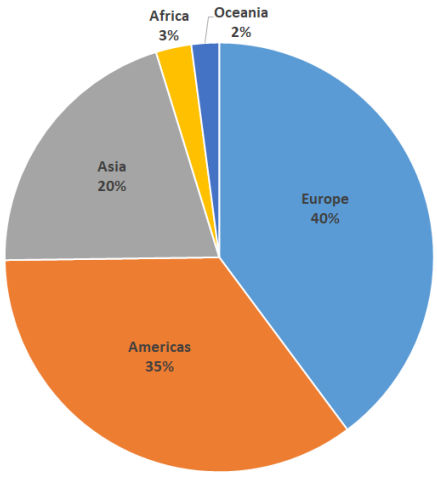
MedDRA is in 127 countries

MedDRA Users Profile

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



MedDRA Users by Region



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

Subscribing to 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

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)

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

MedDRA 2021 Subscription Rates

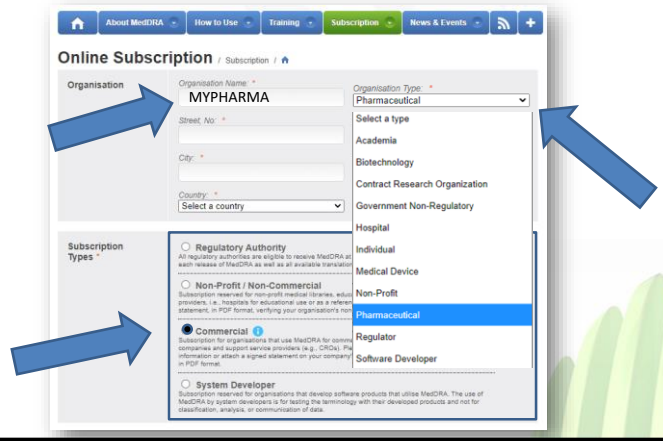
MedDRA Subscription Types	2021 Annual Subscription Rates
Regulatory Authority	$0 USD
Non-Commercial / Non-Profit	$0 USD
Commercial (Parent Company Annual Revenue or Turnover)	
Level 0 (Annual Revenue < $1 Million)	$154 USD
Level 1 (Annual Revenue $1-$10 Million)	$854 USD
Level 2 (Annual Revenue $10-$20 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

Subscription Process

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

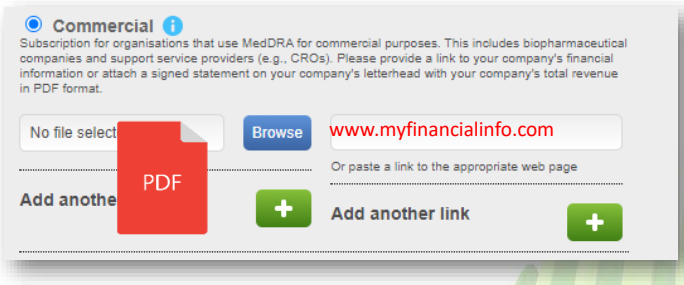
Subscription Process (cont)

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

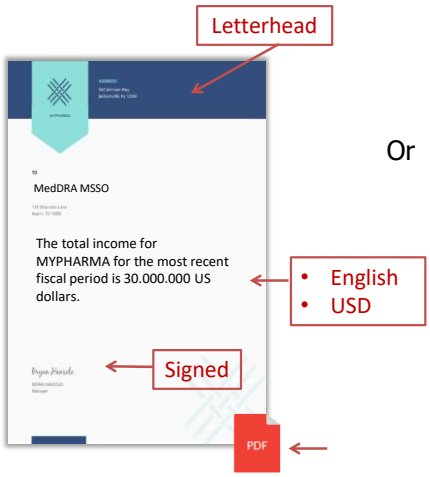


Subscription Process (cont)

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

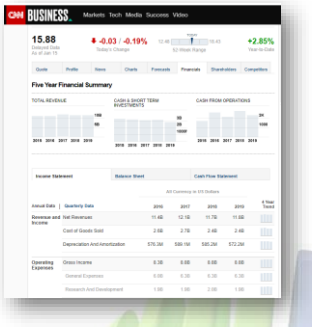


Commercial License Financial Information



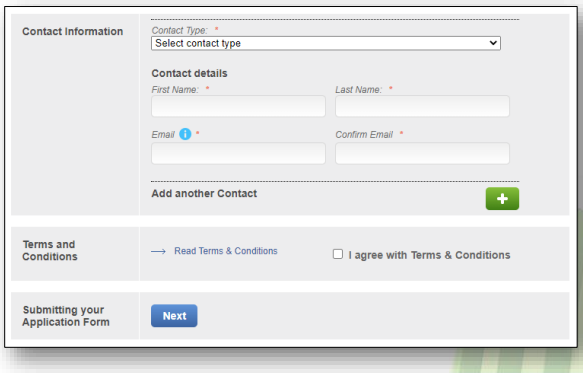
Or

www



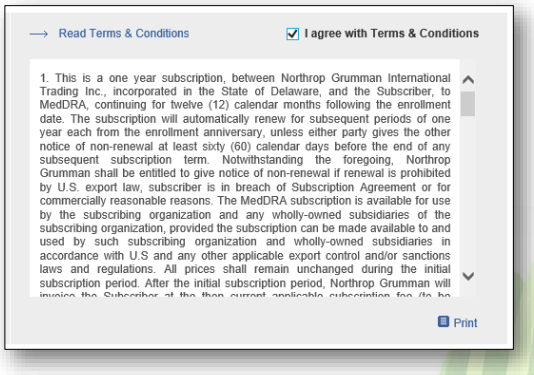
Subscription Process (cont)

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)



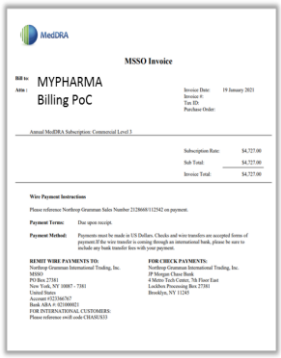
Subscription Process (cont)

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



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

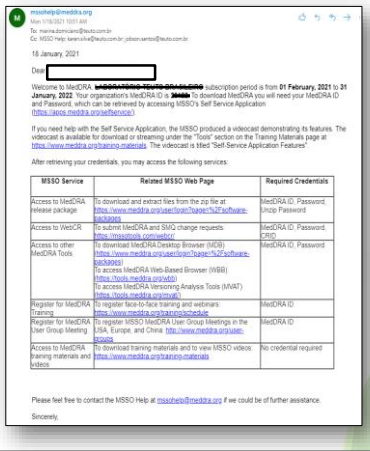
MYPHARMA
Billing PoC

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

Subscription Process (cont)

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



18 January, 2021

Dear [redacted]

Welcome to MedDRA [redacted] subscription period is from **01 February, 2021** to **31 January, 2022**. Your organization's MedDRA ID is [redacted]. To download MedDRA you will need your MedDRA ID and Password, which can be retrieved by accessing MSSO's Self Service Application (https://apps.meddra.org/selfservice/).

If you need help with the Self Service Application, the MSSO produced a videocast demonstrating its features. The videocast is available for download or streaming under the "Tools" section on the Training Materials page at https://www.meddra.org/training-materials. The videocast is titled "Self-Service Application Features"

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/user?login?page=%2Fsoftware-packages	MedDRA ID, Password, Unzip Password
Access to WebCR	To submit MedDRA and SMQ change requests https://mssotools.com/webcr/	MedDRA ID, Password, CRID
Access to other MedDRA Tools	To download MedDRA Desktop Browser (MDB) https://www.meddra.org/user/login?page=%2Fsoftware-packages) To access MedDRA Web-Based Browser (WBB) https://tools.meddra.org/wbb/ To access MedDRA Versioning Analysis Tools (MVAT) https://tools.meddra.org/mvat/	MedDRA ID, Password
Register for MedDRA Training	To register face-to-face training and webinars: https://www.meddra.org/trainingschedule	MedDRA ID
Register for MedDRA User Group Meeting	To register MSSO MedDRA User Group Meetings in the USA, Europe, and China: http://www.meddra.org/user-groups	MedDRA ID
Access to MedDRA training materials and videos	To download training materials and to view MSSO videos: https://www.meddra.org/training-materials	No credential required

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

Sincerely,

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

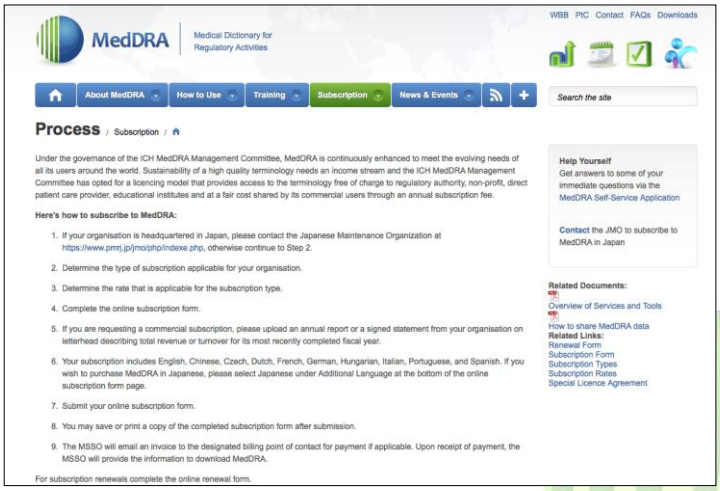
Data may be freely exchanged between current MedDRA subscribers

Violation

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

MedDRA Data Sharing (cont)

- For details, see the Statement on MedDRA Data Sharing



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

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	Abdomen enlarged	0711	Abdomen enlarged	10000045	Abdominal distension	10000060
3	Abdominal adhesions	1559	Abdominal adhesions	10000050	Abdominal adhesions	10000050
4	Abdominal pain	0268	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	1933	Abnormal palmar/plantar creases	10000162	Abnormal palmar/plantar creases	10000162
8	Abortion	0634	Abortion	10000210	Abortion	10000210
9	Abortion missed	0635	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	Abscences	1208	Absence seizure	10000331	Petit mal epilepsy	10034759
13	Abscess	0887	Abscess	10000269	Abscess	10000269
14	Acanthosis	1052	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	Achalasia cardiae	1152	Achalasia cardiae	10000422	Oesophageal achalasia	10030136
19	Acid-base balance disorder mixed	2238	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

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

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

Downloading MedDRA Release Files

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

Accessing the MedDRA Browsers

MSSO's MedDRA Browsers

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

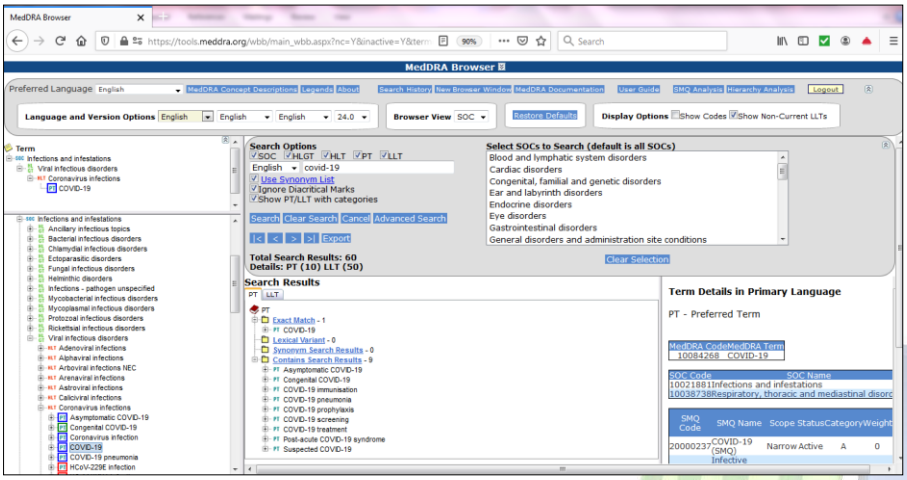
MedDRA Web-Based Browser (WBB)
https://tools.meddra.org/wbb/

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)

Web-Based Browser



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

Overview of MedDRA Tools and Services

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

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

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

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

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

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

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)

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

MedDRA Versioning

A Question You Might Be Asking

"I already have an old version of MedDRA.

Why do I need to keep subscribing every year?"

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

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

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)

Course Summary

In this course, we:

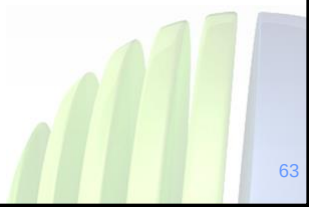
- Described MedDRA and who uses it
- Described the process for subscribing to MedDRA
- Discussed MedDRA implementation topics
- Described tools, services, and training offered with a MedDRA subscription
- Discussed the reasons for a MedDRA versioning strategy

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)

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

MedDRA

Question and Answer Session