



MedDRA
Medical Dictionary
for Regulatory Activities

What's New with MedDRA Version 29.0 and the MSSO



ICH
harmonisation for better health

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MedDRA

Webinar Introduction



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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 Steering Committee. The MedDRA SC is composed of the EC, Europe; EFPIA; FDA, United States; Health Canada, Canada; JPMA; MHLW/PMDA, Japan; MHRA UK; PhRMA; and WHO (as Observer). In addition, since May 2025, the following representatives have been appointed by the ICH MC to join the MedDRA SC and will serve until the next appointment in 2028: NMPA, China; SFDA, Saudi Arabia; and IFPMA (as Observer).

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MedDRA

Topics

- What's New with MedDRA Version 29.0
 - Summary of Changes (including SMQs)
- Proactive Maintenance
- SMQ Updates
- MedDRA Translations
- Update on *Points to Consider (PtC)* Documents
- Update on MedDRA Mapping Initiatives
- Information Technology Tools Update
- MedDRA User News
- Training Update
- Upcoming Meetings

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MedDRA

What's New with MedDRA Version 29.0

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MedDRA

MedDRA Version 29.0

- Release on 1 March 2026
- A complex release
 - Potential changes at all five levels of MedDRA
- Change request summary:
 - MSSO considered 1,380 change requests, including SMQ requests (not including translation updates)
 - Approved: 1,042
 - Not approved: 333
 - Suspended: 5
- Changes reflect the differences between v28.1 and v29.0

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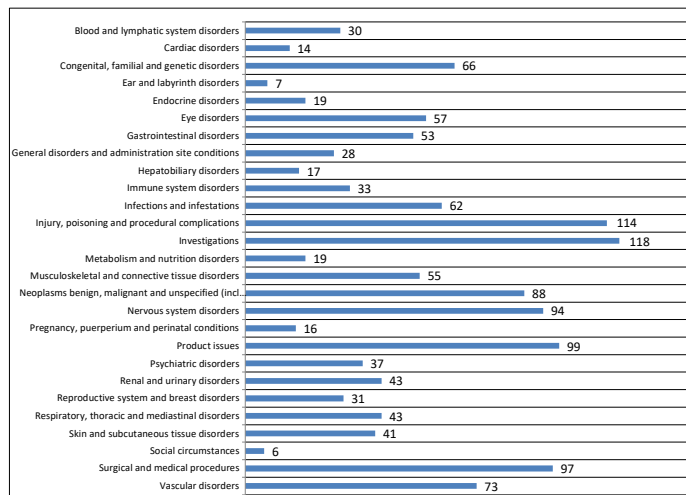
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MedDRA

Net Change of Terms per SOC



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Summary of Complex Changes

- No changes at SOC or HLGT levels
- In Version 29.0, one HLT was added and an existing HLT was merged with this new HLT
- HLT change summary:

New HLT	New HLT	To SOC
	Poliovirus infections	Infections and infestations

Merged HLTs	HLT	To HLT	To SOC
	Poliomyelitis viral infections	Poliovirus infections	Infections and infestations

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Summary of Standardized MedDRA Query Changes

- No new SMQs added in Version 29.0
- As of MedDRA 29.0, there are 110 SMQ Topics
 - Some SMQs are hierarchical (containing subordinate SMQs) which increases the total to 230 individual SMQs
- Maintained with each release of MedDRA
 - 255 PT changes (adds, modifications to existing terms) in MedDRA 29.0
- If you have a need for a new SMQ, use the MSSO [WebCR tool](#) to submit a request
- See MedDRA Version 29.0 SMQ Introductory Guide for detailed information on all SMQs

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MedDRA

Moved Medication Error/Issue Terms

- Based on user requests, the MSSO moved several terms in HLGT *Medication errors and other product use errors and issues* and added some new PTs
- See MedDRA 29.0 Version Report for more details
- Examples:

LLT Name	From PT	To PT
Accidental dose decrease	Wrong dose	Dosing error
Drug maladministration	Product administration error	Product administration issue
Expired drug dispensed	Product dispensing error	Product dispensing issue
Incorrect storage of drug	Product storage error	Product storage issue
Wrong drug product dispensed	Product dispensing error	Product dispensing issue

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Renamed MedDRA Terms

- In Version 29.0, eight MedDRA terms were renamed to correct spelling, spacing, and punctuation. The terms were:

Code	V28.1 Term name	V29.0 Term name	Level
10092556	Intraventricular septum leftward shift	Interventricular septum leftward shift	PT
10085549	Parainfluenzae viral bronchitis	Parainfluenza viral bronchitis	PT
10033796	Parainfluenzae viral infections	Parainfluenza viral infections	HLT
10033797	Parainfluenzae viral laryngotracheobronchitis	Parainfluenza viral laryngotracheobronchitis	PT
10061907	Parainfluenzae virus infection	Parainfluenza virus infection	PT
10049650	Parainfluenzae virus infection NOS	Parainfluenza virus infection NOS	LLT
10035727	Pneumonia parainfluenzae viral	Pneumonia parainfluenza viral	PT
10092783	Videothoracoscopy	Videothoracoscopy	LLT

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New Terms – PT *Suspected off label use*

- New PT *Suspected off label use* added
- LLTs mirror LLTs under PT *Off label use*
- See MedDRA Term Selection:PTC document, Section 3.27.3 for details

PT Off label use

- LLT** Off label dosing
- LLT** Off label dosing amount
- LLT** Off label dosing frequency
- LLT** Off label formulation use
- LLT** Off label fractional dose administered
- LLT** Off label product use duration
- LLT** Off label technique in drug usage process
- LLT** Off label use
- LLT** Off label use in unapproved age group
- LLT** Off label use in unapproved indication
- LLT** Off label use in unapproved route of administration
- LLT** Off label use in unapproved sex
- LLT** Off label vaccine use

PT Suspected off label use

- LLT** Suspected off label dosing
- LLT** Suspected off label dosing amount
- LLT** Suspected off label dosing frequency
- LLT** Suspected off label formulation use
- LLT** Suspected off label fractional dose administered
- LLT** Suspected off label product use duration
- LLT** Suspected off label technique in drug usage process
- LLT** Suspected off label use
- LLT** Suspected off label use in unapproved age group
- LLT** Suspected off label use in unapproved indication
- LLT** Suspected off label use in unapproved route of administration
- LLT** Suspected off label use in unapproved sex
- LLT** Suspected off label vaccine use

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Version Report

Report Title	Total Unique Terms between selected versions
New LLTs including New PTs	611
New PTs	218
Promotions	20
Demotions	40
LLTs under different PTs	218
LLT (excl PT) Primary SOC Chg	21
PT Primary SOC Changes	4
MedDRA Term Name Changes	8
MedDRA Code Switches	0
Currency Changes	35
Complex Changes	2
SMQ Changes	0
PT Changes in SMQs	255
LLT Changes in SMQs	822

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Proactive Maintenance

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Proactivity Request Review

- Proactive maintenance process allows users to highlight inconsistencies or suggest corrections and improvements
- Prior examples included:
 - Review placement of “abrasion” terms
 - Review placement of dental restoration terms
 - Add chemical burn “grade” terms (e.g., first degree) to MedDRA
- Proposals should be sent to mssohelp@meddra.org
- Providing a detailed justification is helpful in evaluation of your request

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Proactivity Request Review (cont)

- One proactivity request implemented in MedDRA v29.0
- A user asked for a review of several LLTs containing the words "secondary malignancy"
- "Secondary malignancy" concept has evolved (i.e., previously was a synonym for metastasis, now considered a new, distinct primary cancer unrelated to previous diagnoses)
- To avoid confusion, 24 "secondary malignancy" terms in MedDRA were made non-current

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Proactivity Request Review (cont)

- Examples of "secondary malignancy" term changes:

LLT Name	V28.1 Currency Status	V29.0 Currency Status	PT Name
Brain secondaries	Current	Non-current	Metastases to central nervous system
Secondary carcinoma	Current	Non-current	Metastasis
Secondary malignant neoplasm of lung	Current	Non-current	Metastases to lung
Secondary malignant neoplasm of skin	Current	Non-current	Metastases to skin

- See MedDRA 29.0 Version Report for more details

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SMQ Updates

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Restructuring of Existing SMQ *Malignant lymphomas*

- Based on user proposal for new SMQ for T-cell malignancies
- MSSO has set up an Expert Group to both develop and test new SMQ proposals
- Expert Group membership consists of international regulatory authorities, industry representatives and clinical/academic practitioners
- Kick-off meeting launched in February 2026
- Expert Group progress will be presented in future What's New updates

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 MedDRA

MedDRA Translations

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MedDRA Translations

Available MedDRA Translations (28)		
Arabic	Brazilian Portuguese	Chinese
Croatian	Czech	Danish (Expected after March 15)
Dutch	English	Estonian
Finnish	French	German
Greek	Hungarian	Icelandic
Italian	Japanese	Korean
Latvian	Lithuanian	Norwegian
Polish	Portuguese	Russian
Slovak	Slovenian	Spanish
Swedish		
Translations Under Development		
Bulgarian	Maltese	Romanian
		Uzbek

- Many of the newer EU translations support electronic Prescribing Information Initiative

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Update on *Points to Consider (PtC)* Documents

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Points to Consider (PtC) Document Changes

- MedDRA Term Selection: PTC
 - Date and version change
 - Changes to
 - Section 2.2 – Quality Assurance
 - Section 3.15 – Medication Errors, Accidental Exposures and Occupational Exposures
 - Section 3.16 – Misuse, Abuse and Addiction
 - Section 3.27 – Off Label Use, including new Sub-Section 3.27.3 Suspected off label use

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Points to Consider (PtC) Document Changes

- Data Retrieval and Presentation: PTC
 - Only editorial updates to date and version
- PTC Companion Document
 - Planned updates to be released in May 2026

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Update on MedDRA Mapping Initiatives

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ICD-10 to MedDRA Mapping

- Latest release published on 26 January 2026, based on:
 - WHO 2019 International Core Version of ICD-10
 - MedDRA Version 28.1 September 2025
- Updated twice annually (next due June 2026)
- Mapping contains approximately 11K terms
- Changes in the latest release include:
 - Re-mapping of 117 ICD-10 terms to a better matching MedDRA Lowest Level Term (LLT) and/or a better matching attribute
 - New mappings of 249 ICD-10 terms that were previously designated as out of scope or unmapped

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MedDRA.org Downloads Page

SSA WBB

Medical Dictionary for Regulatory Activities

Home About MedDRA How to Use Training Subscription News & Events +

Downloads / ↗

The MSSO 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 MSSO Help Desk for any release packages earlier than what is provided above.

MedDRA Desktop Browsers – the MSSO Desktop Browser and the JMO's Desktop Browser are available for download.

- ▶ MedDRA Desktop Browsers

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

- ▶ Supplemental Changes

SNOMED CT – MedDRA Mapping

- ▶ 30 April 2025 SNOMED CT – MedDRA Release Package

ICD-10 to MedDRA

- ▶ 26 January 2026 Release Package

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IMDRF to MedDRA Mapping

- Updated **Annex E** – *Health Effects – Clinical Signs and Symptoms of Conditions*
- Updated mapping from Annex E to MedDRA Version 29.0
- To be published on IMDRF website in March 2026 Consolidated Annexes A-G Workbook
- Updated annually
- [Terminologies for Categorized Adverse Event Reporting \(AER\): terms, terminology and codes | International Medical Device Regulators Forum](#)

JSON Format
 Annex E: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Clinical Signs and Symptoms or Conditions
 JSON (419.01 kb)

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IMDRF to MedDRA Mapping (cont)

- A new collaborative initiative launched in 2025 between IMDRF and ICH with MSSO support:
 - To develop mapping from IMDRF **Annex A** – *Medical Device Problem* to MedDRA
- Annex A terms mapped to best-matching Lowest Level Term (LLT) in MedDRA Version 29.0
 - Reference to IMDRF Annex A term definitions where needed
- Finalized mapped Annex A published on IMDRF website in March 2026 Consolidated Annexes A-G Workbook

JSON Format
 Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Problem
 JSON (171.89 kb)

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SNOMED CT – MedDRA Mapping

- Review currently ongoing in preparation for next SNOMED CT upversion release in April 2026 against MedDRA version 28.1
- Bi-directional mapping updated annually
- Last release was published on 30 April 2025
 - Based on:
 - MedDRA version 27.1 (September 2024)
 - January 2025 release of SNOMED CT International Edition

Version Impact	MedDRA to SNOMED CT	SNOMED CT to MedDRA
2024 Mappings	6779	3946
2025 Mappings	6798	3944
2025 Maps Added	19	31
2025 Maps Deleted	0	33
2025 Maps Updated	119	47

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Information Technology Tools Update

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Download Application Program Interface (API)

- Released on 30 October 2025
- Can download MedDRA data and mapping files via an API
- May be used to automate transfer of MedDRA into your PV system
- Zip files with .asc data will continue to be produced



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API Information

- Where can I go to find information on the Download API and other MedDRA APIs?

The screenshot shows the MedDRA website interface. On the left, a sidebar menu has 'Tools' highlighted with a red box. The main content area features a 'Tools' section with a description of the MedDRA Maintenance and Support Services Organization (MSSO) and its APIs. A QR code is displayed to the right of the 'Tools' section. Below the QR code, there is a 'Related Links' section with a link 'Login for detailed API information' highlighted with a red box. The bottom of the page includes a search bar and a footer with the text 'Direct link: <https://www.meddra.org/meddra-apis>'.

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MedDRA User News

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MedDRA Subscriptions



- MedDRA subscription rates have not been increased since 2005!
 - 2026 rates are unchanged from 2025
- Consider paying for your subscription by credit card
 - Faster and easier payment
 - Easier for MSSO to process

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Phishing Awareness

- Phishing emails most often take the form of an urgent “click here” message
- MSSO email communications will not ask you to verify your account credentials
- When in doubt
 - Don’t click on the link
 - Contact the MSSO Help Desk mssohelp@meddra.org
 - You will be helping to protect yourself and the MedDRA community



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Training Update

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MedDRA LMS Update

- MedDRA LMS is an on-demand e-learning, launched on 7 Jan 2025
- Choice of 3 tracks comprising 8 modules

 Introduction to MedDRA	Track 1: Introduction to MedDRA Course	Module: Introduction to MedDRA
 Basic Coding	Track 2: Basic Coding Course	Module: Overview of MedDRA Coding and Analysis Module: Common Coding Topics Module: Outcomes, Suicide, and Social Circumstances
 Advanced Coding	Track 3: Advanced Coding Course	Module: Special Situations Module: Product-Related topics Module: Pregnancy Module: Interactive Coding

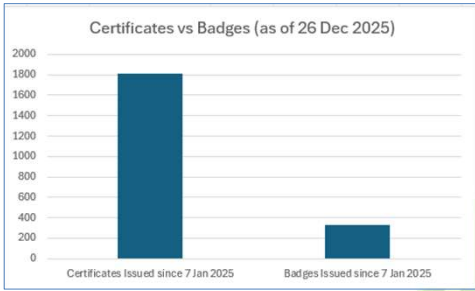
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MedDRA LMS Update (cont)

- In Certificate Track, users undertake multiple modules to earn a downloadable certificate
- In Non-Certificate Track Modules, users select topics of interest and receive online badges in their account
- In 2025, over 1,800 certificates and 300 badges were issued

Certificates vs Badges (as of 26 Dec 2025)



Category	Count (approx.)
Certificates Issued since 7 Jan 2025	1800
Badges Issued since 7 Jan 2025	300

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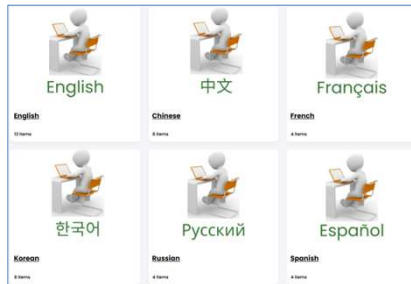
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MedDRA LMS Update – New in 2026

- LMS e-learning is available in 6 languages
- Translations of LMS learning modules are released on a rolling basis



- Track 2 “Basic Coding” in Chinese and Korean are now available

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Joint MedDRA-WHODrug Training

- Two joint MedDRA-WHODrug training classes are scheduled on 23-24 April 2026 in UK
 - Classes immediately follow European MedDRA and WHODrug User Group Meetings in same location
- A comprehensive blended learning course consists of
 - e-learning modules
 - a live introductory webinar
 - in-person training classes

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Joint MedDRA-WHODrug Training (cont)

- In-person sessions will be in an interactive, workshop format to discuss
 - Principles in MedDRA Points to Consider documents
 - Principles in WHODrug Best Practices documents
- Registration is open on meddra.org website under the "Classes of Face to Face Training" tab of the MedDRA Training Schedule page

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In-Person Training Survey

- MSSO initiated a survey on in-person training on 7 November 2025
 - Seeking user feedback on communication of training information and training content, location, etc.
 - Over 400 users worldwide responded to the survey
- The survey link is still active; we encourage everyone to participate if you have not done so already
 - <https://survey.sogolytics.com/r/s9jGBA>



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European User Group Meeting

- Meeting type: Face-to-face, no virtual component
- Date: 22 April 2026
- Time: 8:00 – 16:30 local time
- Meeting Language – English
- Agenda: Available on MedDRA website
- Location: Hatfield, United Kingdom
- Registration: Available online on MedDRA website, deadline is 10 April 2026

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US User Group Meeting

- Meeting type: Face-to-face, no virtual component
- Date: 11 June 2026
- Time: 9:00 – 17:00 local time
- Meeting Language – English
- Agenda: Available on MedDRA website
- Location: Philadelphia, Pennsylvania
- Registration: Available online on MedDRA website, deadline is 28 May 2026

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MedDRA

Chinese User Group Meeting

- Meeting Type: Face-to-face, no virtual component
- Time: May 2026, date to be announced
- Location: Beijing, China
- Meeting Language: Chinese
- Registration: More details to be posted to MSSO Events page on MedDRA Website when available

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LATAM User Group Meeting

- Meeting Type: Face-to-face, no virtual component
- Time: September 2026, date to be determined
- Location: Mexico City, Mexico
- Meeting Language: Spanish
- Registration: More details to be posted to MSSO Events page on MedDRA website when available

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MedDRA

Middle East – Africa User Group Meeting

- Meeting Type: Face-to-face, no virtual component
- Time: October 2026, date to be determined
- Location: Cairo, Egypt
- Meeting Language: English
- Registration: More details to be posted to MSSO Events page on MedDRA website when available

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MedDRA

Korean User Group Meeting

- Meeting Type: Face-to-face, no virtual component
- Time: Late October 2026, date to be determined
- Location: Seoul, South Korea
- Meeting Language: Korean
- More details to be posted to MSSO Events page on MedDRA website when available

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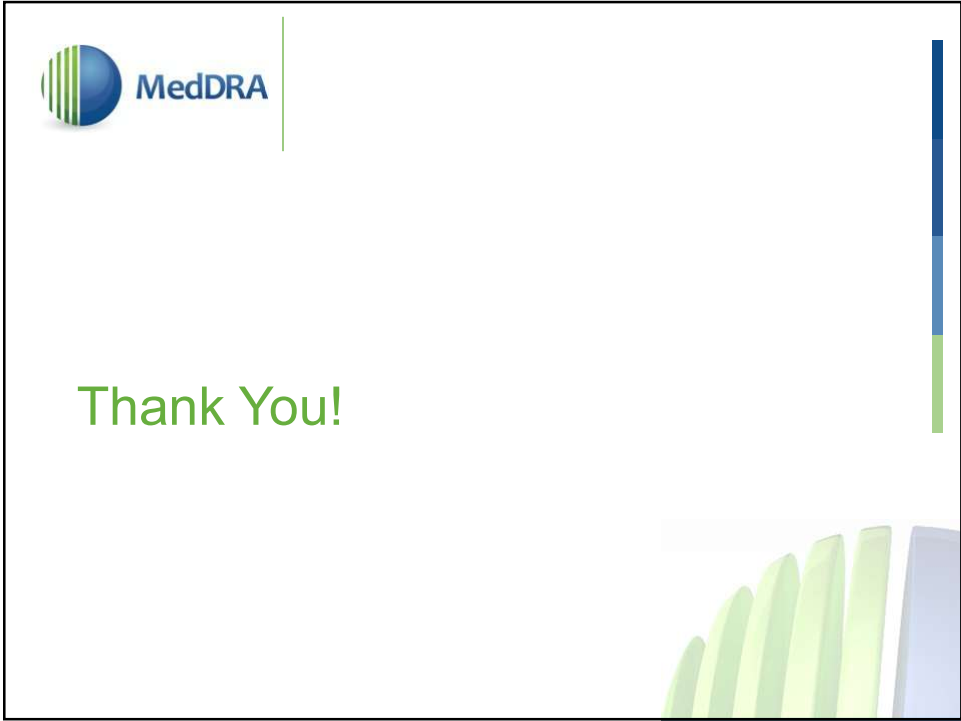
MedDRA Booth Exhibits at Upcoming Meetings

Meeting	Meeting Details
2026 China CMAC	18-20 March 2026 Suzhou, China Booth #A28
ISoP 25 th Global Meeting	22-25 September 2026 San Jose, Costa Rica Booth # - To be announced
World Drug Safety Congress Americas 2026	14-15 October 2026 Boston, Massachusetts Booth #642

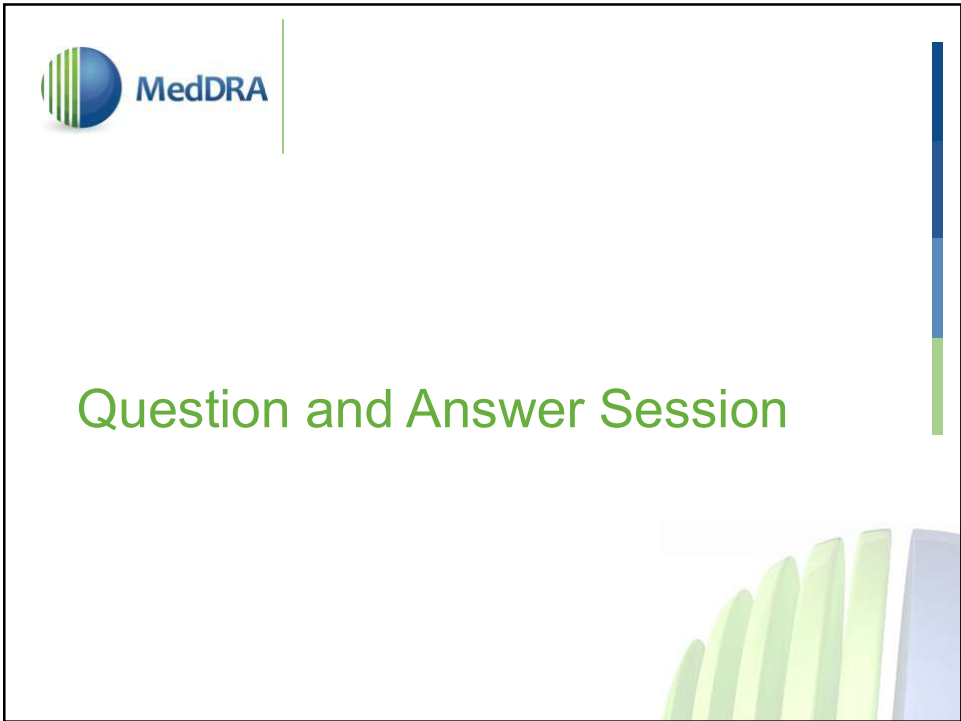
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