



**MedDRA**

# Global Language of Adverse Events

**ФармМедОбращение 2019**

Moscow, Russian Federation

21 May 2019





MedDRA

# What is MedDRA?

**Med** = Medical

**D** = Dictionary for

**R** = Regulatory

**A** = Activities



MedDRA

# MedDRA's Purpose

- Provides a standard used globally
- Provides detail for users to assign MedDRA terms for multiple purposes:
  - Adverse events
  - Medical history
  - Lab tests
  - Indications
- MedDRA provides analytical tools to understand signals and perform analyses
  - Data grouped by MedDRA hierarchy
  - Using Standardised MedDRA Queries (SMQs)
- Supports clear communication



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# ICH Introduction

# ICH

INTERNATIONAL COUNCIL for  
HARMONISATION  
of  
Technical Requirements  
for  
Pharmaceuticals for Human Use  
[www.ich.org](http://www.ich.org)



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# ICH Members

## Regulatory Members

ANVISA, Brazil
CFDA, China
European Commission, Europe
FDA, United States
HAS, Singapore
Health Canada, Canada
MFDS, Republic of Korea
MHLW/PMDA, Japan
Swissmedic, Switzerland

## Industry Members

BIO
EFPIA, Europe
IGBA
JPMA, Japan
PhRMA, United States
WSMI

## Standing Observers

IFPMA

WHO

## Legislative or Administrative Authorities

CDSCO, India

CECMED, Cuba

COFEPRIS, Mexico

INVIMA, Colombia

SAHPRA, South Africa

National Center, Kazakhstan

Rosdravnadzor, Russia

TFDA, Chinese Taipei

TGA, Australia

## Regional Harmonisation Initiatives (RHIs)

APEC

ASEAN

EAC

GHC

PANDRH

SADC

## International Pharmaceutical Industry Organisation

APIC

## International Organisation regulated or affected by ICH Guideline(s)

Bill & Melinda Gates Foundation

CIOMS

EDQM

IPEC

PIC/S

USP



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# ICH and MedDRA

- ICH Role
  - Developed MedDRA as an ICH standard
  - ICH owns MedDRA
  - ICH hired the MedDRA Maintenance and Support Services Organization (MSSO)





# MSSO Role and Responsibilities

- Maintenance and Support Services Organization
  - Maintain, Develop, and Support MedDRA
- Contracted with ICH
- Lead organization for MedDRA's maintenance and development
  - Japanese Maintenance Organization (JMO) supports users in Japan



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# MedDRA Subscriptions

- MedDRA is free to all regulatory authorities and non-commercial users
- Commercial users pay an annual fee based on the organization's annual revenue
  - Commercial subscriptions start at \$160 USD (10,407 ₱) annually
- All users get the same access to MedDRA and MSSO services
  - MedDRA tools, training, User Groups, ability to submit changes





# MedDRA's Scope, Structure, and Use





# MedDRA Structure & Size

MedDRA  
Version 22.0  
(March 2019)

MedDRA Level	Terms at Level
System Organ Class (SOC)	27
High Level Group Term (HLGT)	337
High Level Term (HLT)	1737
Preferred Term (PT)	23708
Lowest Level Term (LLT)	56554

**SOC** - Нарушения со стороны нервной системы

**HLGT** - Головные боли

**HLT** - Головные боли, НКДР

**PT** - Головная боль

**LLT** - Резкая внезапная головная боль



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# 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





# MedDRA in Use

	Lowest Level Term	Preferred Term	High Level Term	High Level Group Term	System Organ Class
English	Asthmatic wheezing	Wheezing	Bronchospasm and obstruction	Bronchial disorders (excl neoplasms)	Respiratory, thoracic and mediastinal disorders
Russian	Астматическое свистящее дыхание	Свистящее дыхание	Бронхоспазм и обструкция	Бронхиальные нарушения (искл. новообразования)	Нарушения со стороны дыхательной системы, органов грудной клетки и средостения

**Coding** – Applied to individual events

**Analysis** – Grouping of multiple events for signal detection



# Using MedDRA

An elderly male took re-vital for one week for fatigue. The patient developed fever, rash, eosinophilia, and diminished renal function. Re-vital was discontinued and the patient was hospitalized. Acute interstitial nephritis was diagnosed and confirmed by renal biopsy. The patient was treated with Diuretics and he subsequently recovered, regaining normal renal function.

- Medical History
- Adverse events
- Diagnosis
- Procedure



# Russian Translation of MedDRA

- MSSO released the first release of MedDRA in Russian on 15 March 2019
  - All MedDRA terms (~80,000 terms)
  - All User Documentation



# MedDRA User Documentation in Russian

 MedDRA	 MedDRA	 MedDRA	 MedDRA
словари	Ввод стандар запросам	Документ с ук дистр	Что нового в MedDRA версии 22.0
			Март 2019 г. 000271

## What's New Document



MedDRA

# Russian Review Team

- MSSO hired a medical translation firm to perform the initial translation
- Roszdravnadzor and Russian industry (AIPM) formed a Review Team that reviewed the translation (terms and documentation)
- Significant effort that led to a greatly improved product





MedDRA



Sergey  
Glagolev



Vitaly  
Polivanov



Boris  
Romanov



Renad  
Alyautdin



Elena  
Obernikhina



Almira  
Galeeva



Ivan  
Anosov



Anna  
Beme



Victoria  
Borisovskaya



Valeriy  
Bystrov



Tatiana  
Chechendaeva



Vadim  
Vadnogolov



Evgeny  
Chudakov



Anna  
Erenburg



Julia  
Ilkovich



Kirill  
Gorelov



Karina  
Kamaeva



Olga  
Kapitonova



Alexander  
Kazakov



Lola  
Khodzhayova



Julia  
Koroleva



Rustam  
Kuliev



Olesya  
Merzlyakova



Olga  
Orlova



Artem  
Osokin



Anastasia  
Ovchinnikova



Evgeny  
Pashanov



Jeffrey  
Poplavsky



Tatyana  
Prokhorova



Olga  
Selezneva



Svetlana  
Sergievskaya



Elizaveta  
Spiridonova



Irina  
Tertychnaya



Anna  
Torubarova



# MedDRA Translations

- Currently MedDRA is available in 12 languages
  - Chinese, Czech, Dutch, English, French, German, Hungarian, Italian, Japanese, Portuguese, Russian and Spanish
- Currently developing MedDRA translations in Korean and Brazilian Portuguese
  - Release dates for the new languages are to be determined



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# Codes and Languages



Electronic Submission



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# Why Use MedDRA?





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# Goal of MedDRA

- Promote patient safety
  - Internationally recognized terminology used by regulatory authorities and industry
    - Pre- and post-marketing
  - Support the global exchange of clinical information
    - Industry to regulator
    - Industry to industry (partners)
    - Regulator to regulator

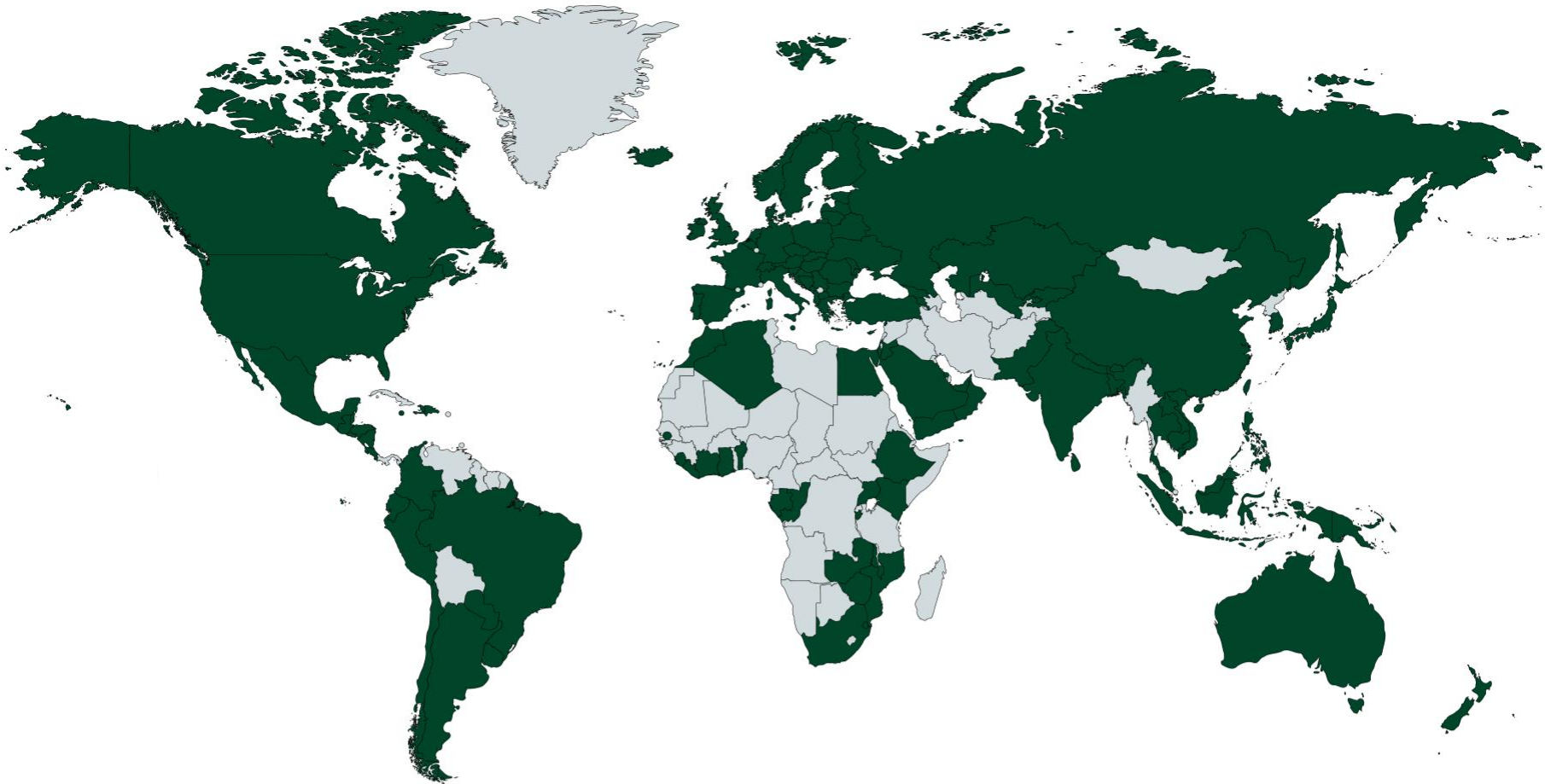






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# MedDRA Users By Country





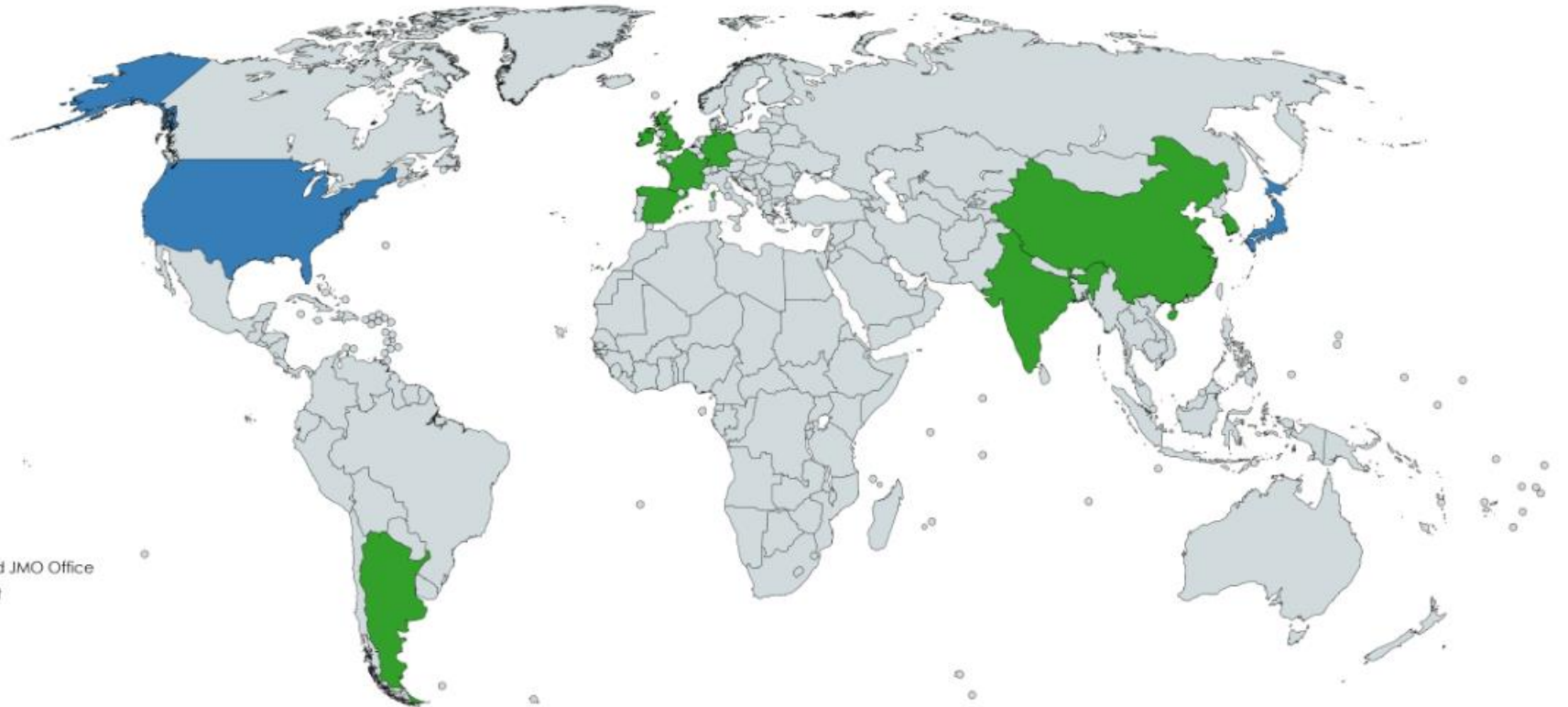
# Goal of MedDRA (cont)

- Designed to support regulatory reporting
  - Integrated into other ICH standards E2B(R2/R3) Individual Case Safety Report (ICSR)
- Includes needed features
  - Granularity to support accurate coding of cases
  - Embedded analysis tools to support signal detection
- Rigorous maintenance process
  - Updated twice a year based on user requests



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# MSSO Staff Around the World



■ MSSO HQ and JMO Office  
■ Local Support





**MedDRA**

Medical Dictionary  
for Regulatory Activities

Thank You

Questions?

