



# MedDRA: an ICH Success Story

**ASEAN MedDRA Training  
Kuala Lumpur, March 17-19, 2010**

**Dr. Christina Winter**, Medical Director  
Global Clinical Safety & Pharmacovigilance  
GlaxoSmithKline R&D  
EFPIA ICH MedDRA Management Board Member

International Conference on Harmonisation of Technical  
Requirements for Registration of Pharmaceuticals for Human Use



# ICH

INTERNATIONAL CONFERENCE ON  
HARMONISATION  
of  
Technical Requirements  
for the Registration of  
Pharmaceuticals for Human Use

<http://www.ich.org>

Hosted by ICH Secretariat  
IFPMA-Geneva, Switzerland



## The ICH Members

Europe	<b>EC</b> – European Commission – European Union (EU) <b>EFPIA</b> - European Federation of Pharmaceutical Industries and Associations
Japan	<b>MHLW</b> - Ministry of Health, Labour and Welfare <b>JPMA</b> - Japan Pharmaceutical Manufacturers Association
United States	<b>FDA</b> - Food and Drug Administration <b>PhRMA</b> - Pharmaceutical Research and Manufacturers of America
Observers	WHO – World Health Organization Health Canada EFTA – European Free Trade Association

*...Expanding beyond ICH regions*



3

## ICH Accomplishments

- Well-defined objective of ICH: improve efficiency of new drug development and registration process
- Accomplished through harmonization by defining:
  - common Technical requirements (close to 60 Quality/Safety/Efficacy guidelines)
  - common Registration format (CTD/eCTD)
  - common Medical terminology - MedDRA



4

# MedDRA

**Med** = Medical  
**D** = Dictionary for  
**R** = Regulatory  
**A** = Activities

## Objectives for MedDRA Development

To support drug safety monitoring, by providing:

- An international multi-lingual terminology
- Standardized communication between industry and regulators
  - Within regions and between regions
- Support for electronic submissions of Individual Case Safety Report (*ICSR*)
- A terminology for use through all phases of development cycle
  - Clinical trials
  - Post-marketing

## ICH Guidance – How to use MedDRA?

- Establishment of the ICH MedDRA Points to Consider (PtC) Working Group in 1999
- ICH MedDRA Points to Consider Documents:
  - How to best classify the data? *MedDRA Term Selection document*
  - How to best retrieve and present the data? *MedDRA Data Retrieval and Presentation document*
  - Both updated with Users feedback for every release of MedDRA

**MedDRA POINTS TO CONSIDER**  
**<http://www.ich.org>**



7

## MedDRA Governance MedDRA Management Board

- ICH Board appointed by ICH to oversee MedDRA
- Consists of:
  - 6 ICH Parties: **EU, EFPIA, FDA, PhRMA, MHLW** and **JPMA**
  - **MHRA** (Medicines and Healthcare products Regulatory Agency of the UK)
  - **Health Canada**
  - **WHO** (participates as Observer)
- Chaired by IFPMA/ICH Secretariat



8



## IFPMA

### International Federation of Pharmaceutical Manufacturers & Associations

- Non-Profit, Non-Governmental Organisation
- Represents national industry associations and R&D companies from developed & developing countries
- Provides the ICH Secretariat
- Holds ownership of MedDRA, as a trustee of ICH
- Contracts for the maintenance organisation of MedDRA (MSSO)



9



## MSSO

### Maintenance and Support Services Organisation

- Contracted by IFPMA, as a trustee of ICH (Nov 1998-)
- Activities directed by the ICH MedDRA Management Board
- Exclusive license for maintenance and distribution (twice a year) of MedDRA
- Provides services to Subscribers - Help Line / Repository of MedDRA information / Training



10

# JMO

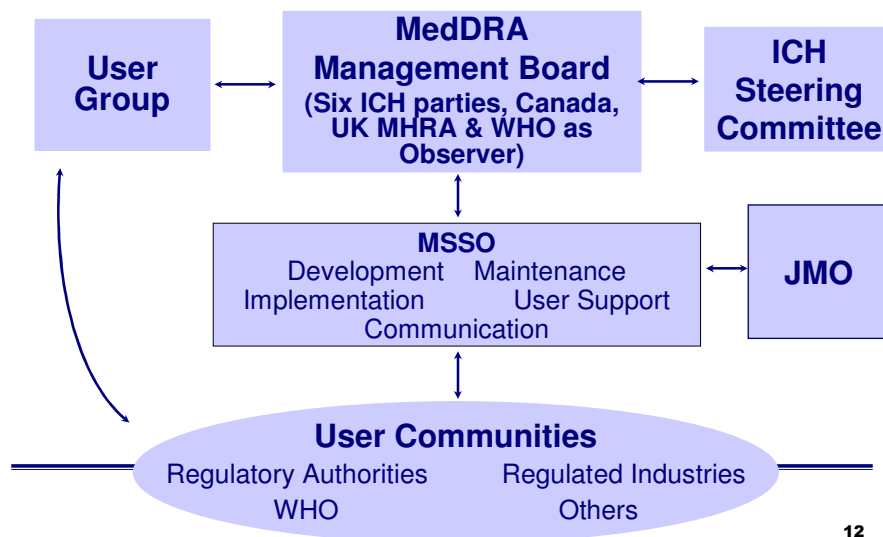
## Japanese Maintenance Organization

- MedDRA MSSO partner
- Provides MedDRA subscription service to companies headquartered in Japan
- Maintains and distributes MedDRA/J
- Assists MSSO in providing MedDRA related information and services in Japan
- Japanese Management Board (JMB) composed of MHLW, JPMA & FPMAJ
- JMB provides reports to the ICH MedDRA Management Board



11

## ICH Management Structure of MedDRA



12

## MedDRA Management Board Purpose & Responsibilities

- Major responsibilities
  - Oversees financial and technical operations of the MSSO
    - Examples: Review MSSO costs and fee structure
  - Ensures the continued development and viability of MedDRA
  - Ensures that MedDRA is easy to use and accessible to all
  - Ensures MSSO is meeting the needs of users



13

## MedDRA Management Board *Latest news*

- Recent MedDRA Management Board Decisions:
  - Supported the integration of MedDRA into WHO Global ICSR Database
  - In addition to being free to all regulators, fees eliminated for other subscribers
  - Instructed MSSO to offer free training for all MSSO Subscribers
  - Agreed to the development of a Web-based MedDRA browser (*Launched January 2010*)
  - Endorsed the development of Chinese Mandarin translation of MedDRA (*Released September 2009*)



14

## Integration of MedDRA into WHO ICSR Database (Vigibase)

- As of March 2008 MedDRA is integrated in WHO's Vigibase
  - Vigibase process now as compatible with MedDRA as they are with WHO-ART
    - Data can be entered in either MedDRA or WHO-ART
    - Outputs can be displayed in either WHO-ART or MedDRA
- With Vigibase containing > 4 million ICSRs, it now provides a global repository of MedDRA-coded safety data
  - Substantial tool for pharmacovigilance
  - Of significant benefit to patient safety and public health

## Facilitating use of MedDRA

- In 2008, the MedDRA Management Board authorized the MSSO to offer free training for all MSSO subscribers
  - Free training on coding and data analysis
  - Offered at various locations in EU and US
  - Free Webinars also offered
- Part of the MedDRA Management Board's policy to reduce barriers to MedDRA's use
  - Comes in addition to other moves such as the recent elimination of subscription fees\* for small business, not-for-profit, and academic organizations

\* It should be noted that a subscription to MedDRA is **free** for all Regulators!



## Development of a MedDRA Web-Based Browser

- As of January 2010, in addition to current Desktop MedDRA Browser, MSSO Subscribers now have the option to use a Web-based MedDRA Browser
  - Offered as part of MSSO subscription to MedDRA at no extra cost
  - Subscribers can log-in online to view and search any version and translation of MedDRA
  - Expected to be of particular benefit to Subscribers without access to sophisticated IT infrastructures

## Development of a Mandarin Chinese Translation of MedDRA

- ICH MedDRA Management Board recognizes importance of globalization:
  - Need to engage with non-ICH countries
    - ⇒ Development of a **Mandarin Chinese Translation** of MedDRA (*Released September 2009*)

# CONTACT US!

How to discuss policy matters with the ICH  
MedDRA Management Board?



through the ICH Secretariat:  
[meddraboard@ich.org](mailto:meddraboard@ich.org)