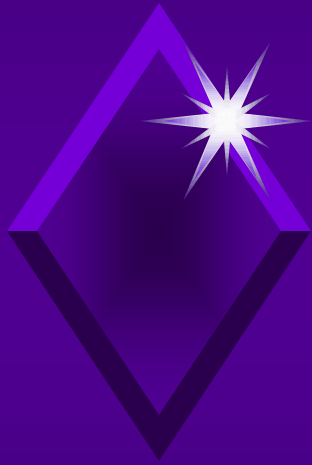


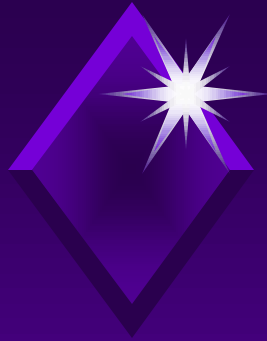
*Status of Regulatory
Implementation by MHW*



November 9, 2000

Takashi Yasukawa

Ministry of Health and Welfare, Japan



ICH Topics

◆ M1

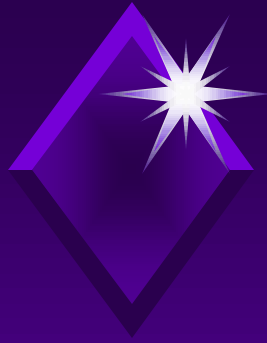
Medical Terminology

◆ E2B

Data Elements for Transmission of ADR
Reports

◆ M2

Electronic Standards for the Transfer of
Regulatory Information and Data (ESTRI)



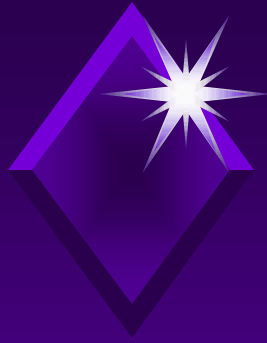
Implementation Plan in Japan

- ◆ **STEP 1: Adoption of MedDRA/J**

Notification December 28, 1999

- ◆ **STEP 2: A pilot test based on E2B/M2**

- ◆ **STEP 3: Implementation of electronic ICSR**

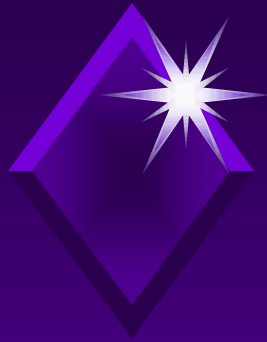


Adoption of MedDRA/J

◆ Administrative Notification

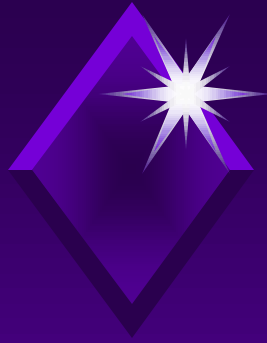
“ Use of the Japanese Version of MedDRA (MedDRA/J) ” (December 28, 1999)

- Basic Principle
- Date of effectuation
- Scope of application
- Notes



Basic Principle

- ◆ MedDRA/J ADR terms may be used in ADR and infection case reports from industry
 - J-ART (Japanese Adverse Drug Reaction Terminology) remains applicable for the time being
- ◆ Use of MedDRA/J as ADR terms is recommended.
- ◆ MedDRA/J may also be used to describe ADRs in the following
 - Clinical trial reports
 - Re-examination / Re-evaluation of drug reports
 - Package inserts (if possible)



Date of effectuation and scope of application

◆ Date of effectuation

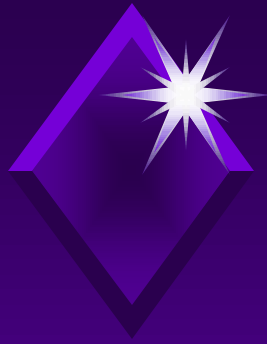
The end of March 2000

◆ Scope of application

ADR and infection case reports from industry

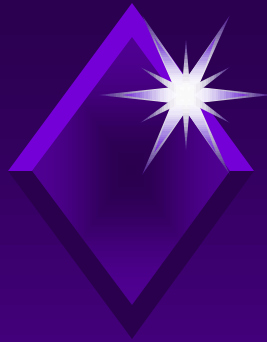
- History of ADRs
- ADRs / infections

Reporting level: Preferred Term



Present state

- ◆ The number of Reports with MedDRA/J terms
 - About 20% of all the reports from industry
- ◆ Increase expected in future
 - Solution to the PT-LLT issue as reporting terms
 - Implementation of the electronic reporting system based on ICH topics (E2B/M2)



Coming Issues regarding MedDRA

- ◆ Practical use of “MedDRA Term Selection: Points to Consider”
- ◆ Numeric code
 - necessary for the exchange of information among the multiple language regions
- ◆ Version control
 - necessary for the management of MedDRA since MedDRA is revised periodically
- ◆ Expansion of the application scope
 - “Indication for use” in E2B data element
 - PSUR etc.