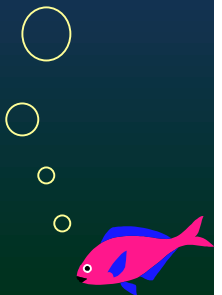


# Experiences of using MedDRA in Japanese Industry

Tadao AKIYAMA

Information Management  
Japan Drug Surveillance  
Pharmacia&Upjohn

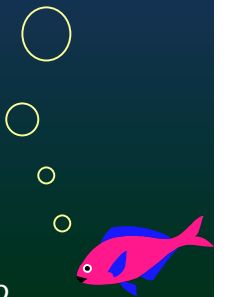
MedDRA user ICH5 Meeting 9/November/2000



# Today's Topics



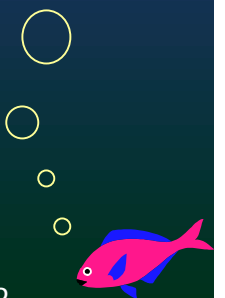
- Background
- Benefit of MedDRA
- What to be considered
  - Industry
  - Regulatory



# Background(1) : Regulation in Japan

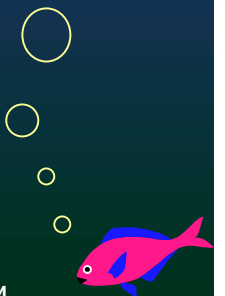


- Acceptable from March 31, 2000  
(J-ART is also acceptable)
  - Adverse Reaction in Expedited Report
  - Periodic Safety Report
  - Re-examination Document
  - Adverse Reaction in Package Insert
- PT should be used in Expedited Report

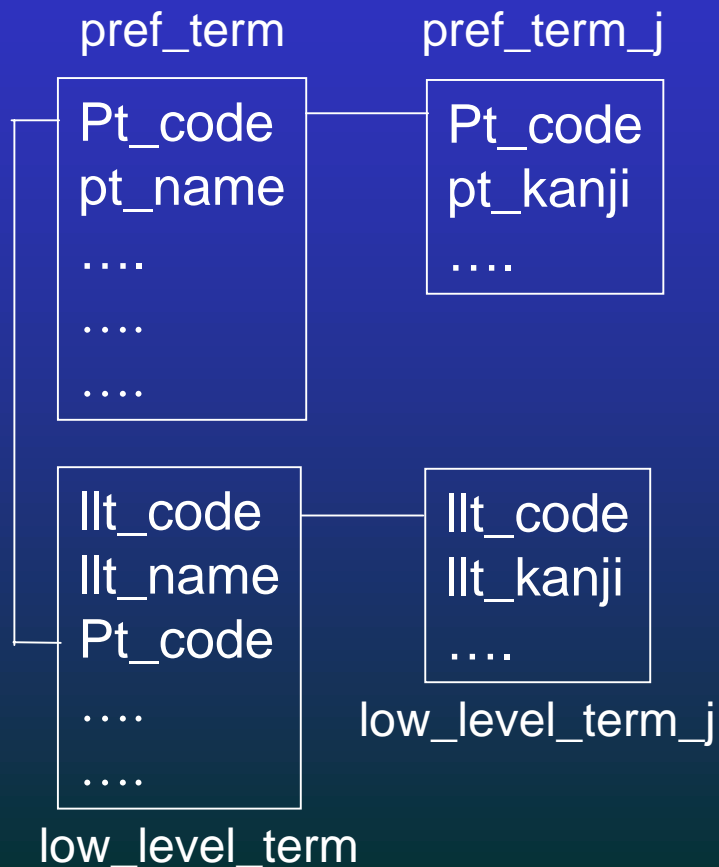


## Background(2): MedDRA/J

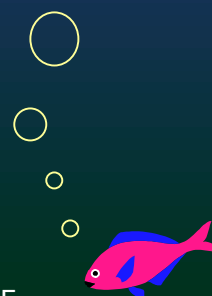
- The same term and the same code as MedDRA, but includes Japanese term
- Includes J-ART code
- Additional files for Japanese term
  - e.g. `pref_term_j`, `low_level_term_j`
- Japanese translation is Not one to one relation
- Japanese current flag
- Provided by JMO



# Background(3): Table structure of MedDRA/J



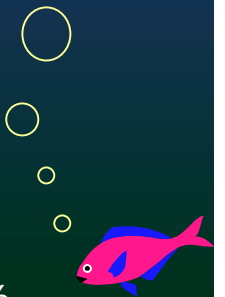
pt_code	pt_name	pt_kanji
10000050	Abdominal adhesions	XXXXXX
10000060	Abdominal distension	#####
10000068	Abdominal hernia NOS	%%%%%%%%
10000069	Abdominal hernia NOS gangrenous	\$\$\$\$\$\$\$
10000070	Abdominal hernia NOS, obstructive	&&&&&&



# Where MedDRA can be implemented



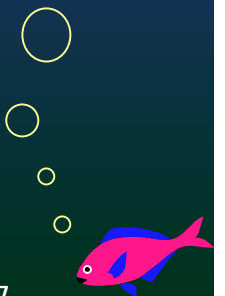
- Safety Information Management
  - Clinical trial
  - Marketed Product
- Regulatory reporting
  - Single case report
  - Summary report
- Product information



# MedDRA applicable fields ICH E2B



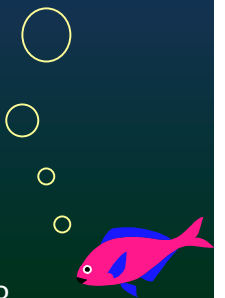
- New ICH E2B document(not agreed yet)
  - Name of reaction/event
  - Indication
  - Relevant medical history



# Benefit of MedDRA



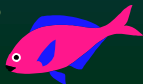
- Available world-wide
- Precise communication between HQ and foreign branch office
- Global maintenance
- New version releases at the same time world-wide
- Provided as electronic file



# Coding with MedDRA



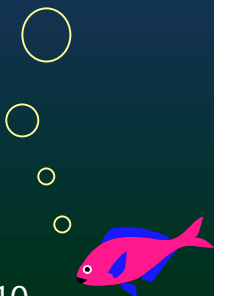
- Coding of reported information
  - From reported term to MedDRA term
- Legacy data transfer
  - From the term coded with non MedDRA dictionary to MedDRA term
- Re-coding
  - From the term coded with previous version to current MedDRA term



# To be considered in Industry(1): Legacy data transfer

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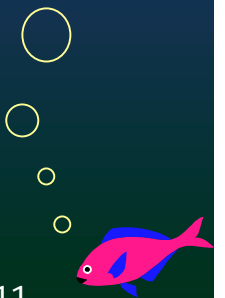
- Coding from J-ART or reported term?
- How process should be verified and validated?



# To be considered in Industry (2): Re-coding



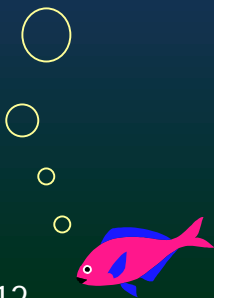
- Summary reports
- Need standard procedure
- How process should be verified and validated?



# To be considered in Industry(3): Version control



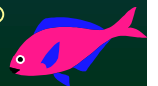
- Recommendation of MSSO
- Tools
- Business process



# To be considered in Industry(4): Training



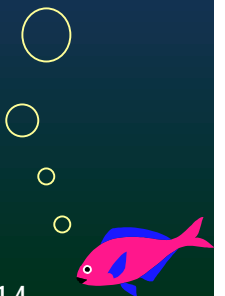
- For Case Manager
- For IT person
  - Coding with MedDRA is not so difficult
  - Legacy data transfer requires both medical and IT knowledge
  - Not only training for coding but one for technical issues are required



# To be considered in Regulatory(1): MedDRA applicable field



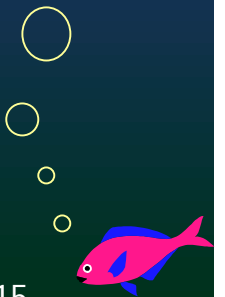
- MedDRA applicable field in E2B
  - Agreed as for Reaction/event field
  - How about other field?
  - Discrepancy might cause trouble



# To be considered in Regulatory(2): Control of Coding



- The same reported term should be coded to one term
- During a pilot with 18 participants, variety of coded term was found
- Inside a industry
- Inside a country
- World-wide



# Requests to MSSO/JMO



- Less frequent version-up
- 2byte Kana in MedDRA/J
- Version information somewhere in ASCII files
- Price

