



# MedDRA MSSO User Group Meeting

US DIA, Washington DC  
17 June 2004

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Pharmaceutical Manufacturers Associations (IFPMA)



# Agenda

## 1. Welcome and Introduction

Pat Revelle

## 2. Regulatory Update

- US FDA
- EMEA
- JMO
- Questions and Answers

Andrea Feight  
Sabine Brosch  
Yasuo Sakurai

## 3. Networking Break (20 minutes)

## 4. MedDRA Discussion Topics

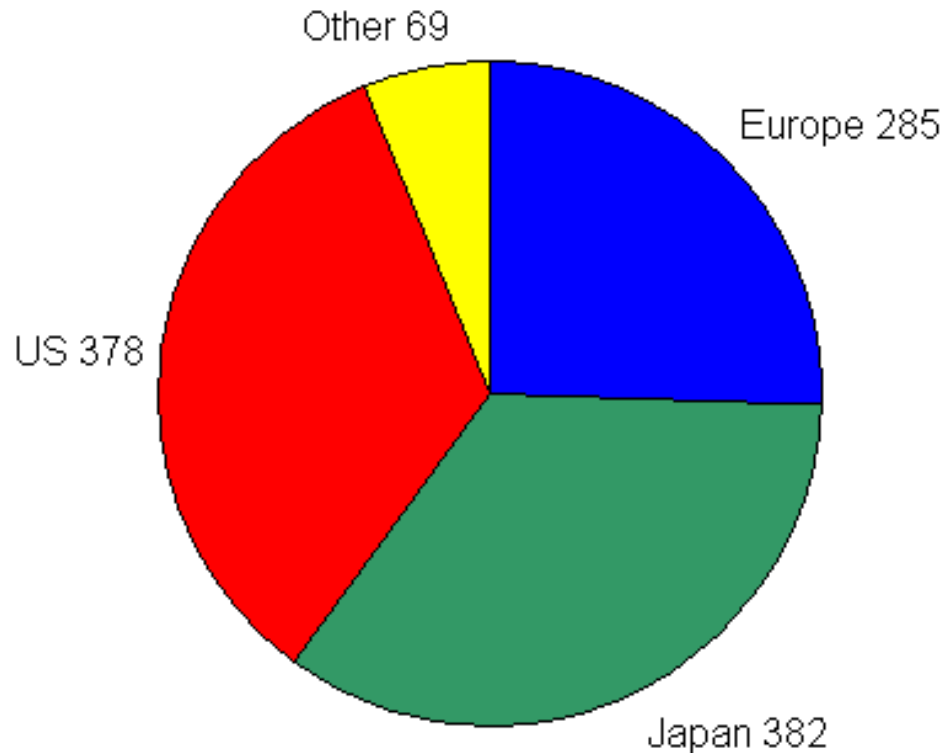
- SMQs
- Versioning
- MedDRA Encoding by Investigators

Patricia Mozzicato  
Pat Revelle  
Patricia Mozzicato

## 5. Questions and Answers



# MedDRA Update



1,114 Subscribers to MedDRA Worldwide



# MedDRA Dates

## MedDRA 7.1

- Freeze date
  - 25 June 2004
- Release date
  - 1 September 2004

## MedDRA 8.0

- Complex Change web postings for comment
  - 1 July 2004
  - 15 November 2004
- Freeze date
  - 17 December 2004
- Final list of Complex Changes
  - 15 January 2004
- Release date
  - 1 March 2005



# MedDRA Distribution

- Starting with MedDRA 7.1 (1 September 2004) MSSO will make MedDRA available as a download from the MSSO website
- CD-ROM distribution will continue
  - In future, subscribers can choose distribution method (download or CD-ROM)
- Download (2.5MB zip file) contains
  - ASCII files (full and sequential)
  - All release documentation



# MedDRA Distribution Process

1. Subscriber point of contact receives (in mail) zip file password
2. Subscribers use normal User ID and password to enter subscriber section of website
3. Download MedDRA zip file
4. Unzip MedDRA file using zip file password (provided in step 1)



**Thank you**