



International
User Group Meeting
Basel, Switzerland
5 March 2002





Agenda

- MSSO Overview
- MedDRA Implementation
- Status of Regulatory Implementation
- Questions and Answers
- Networking Break

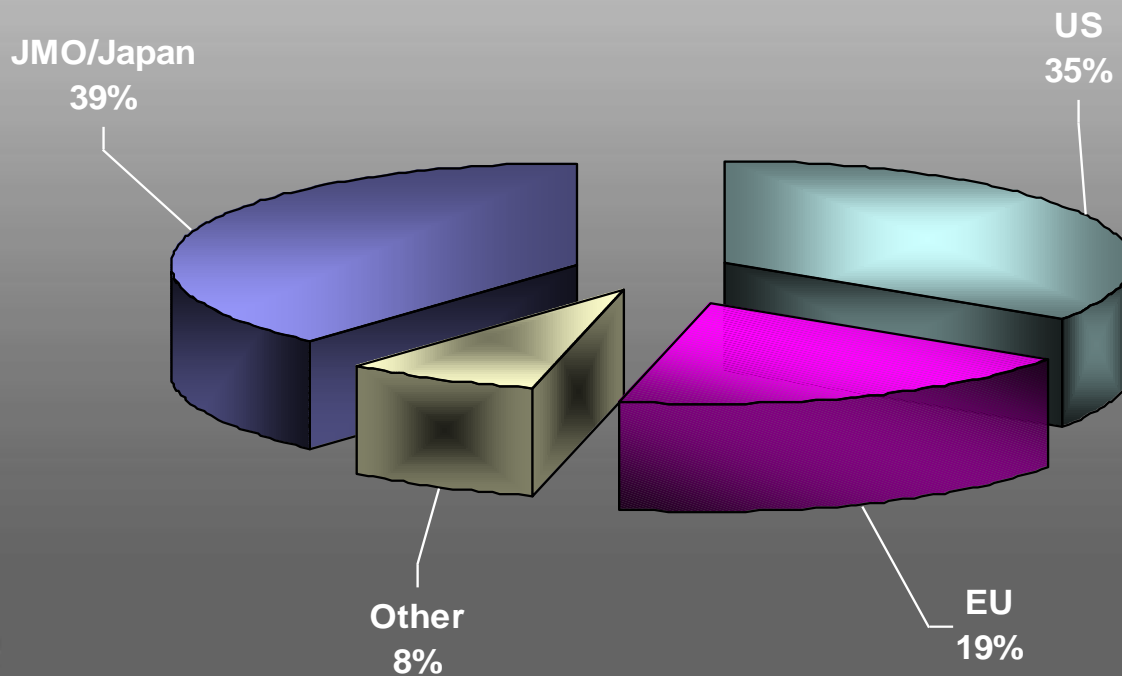
Break out sessions

- MedDRA in Pharmacovigilance
 - Signal Detection
 - Why your Data may look different
- Use of MedDRA in Clinical Trials
 - Data Collection and Analysis
 - Other data points besides Adverse Events



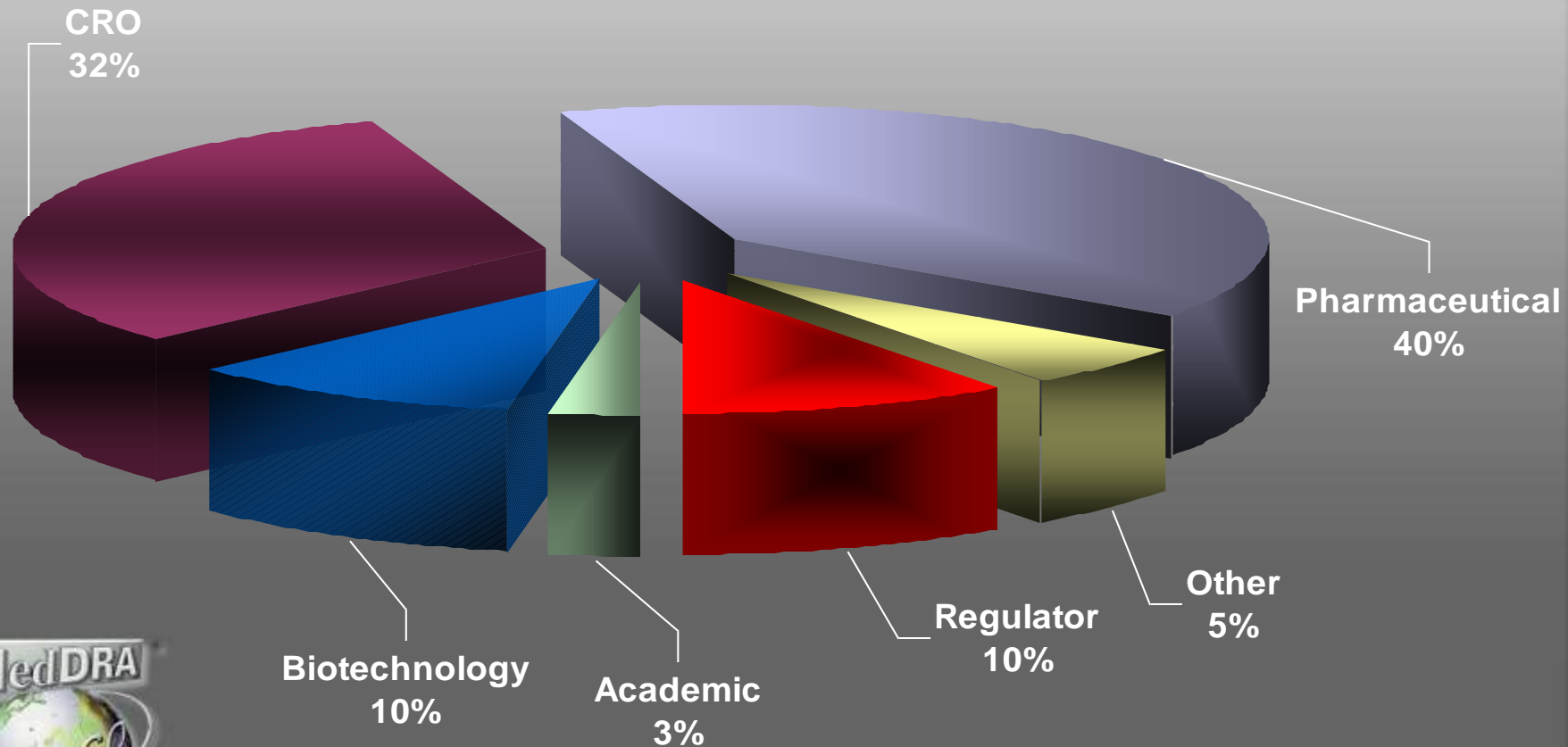


MedDRA Subscriptions Percent by Region



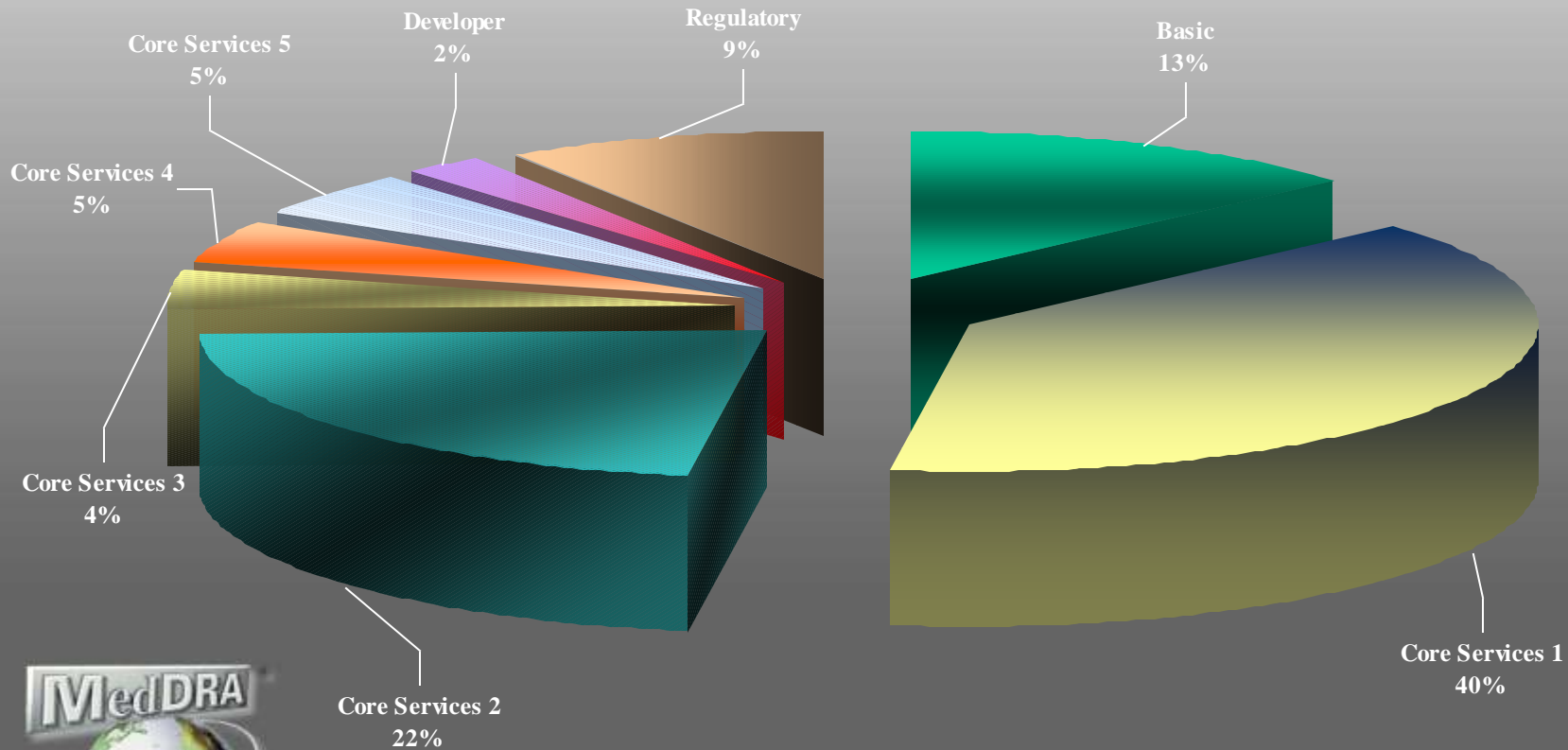


MedDRA Subscriptions Percent by Category



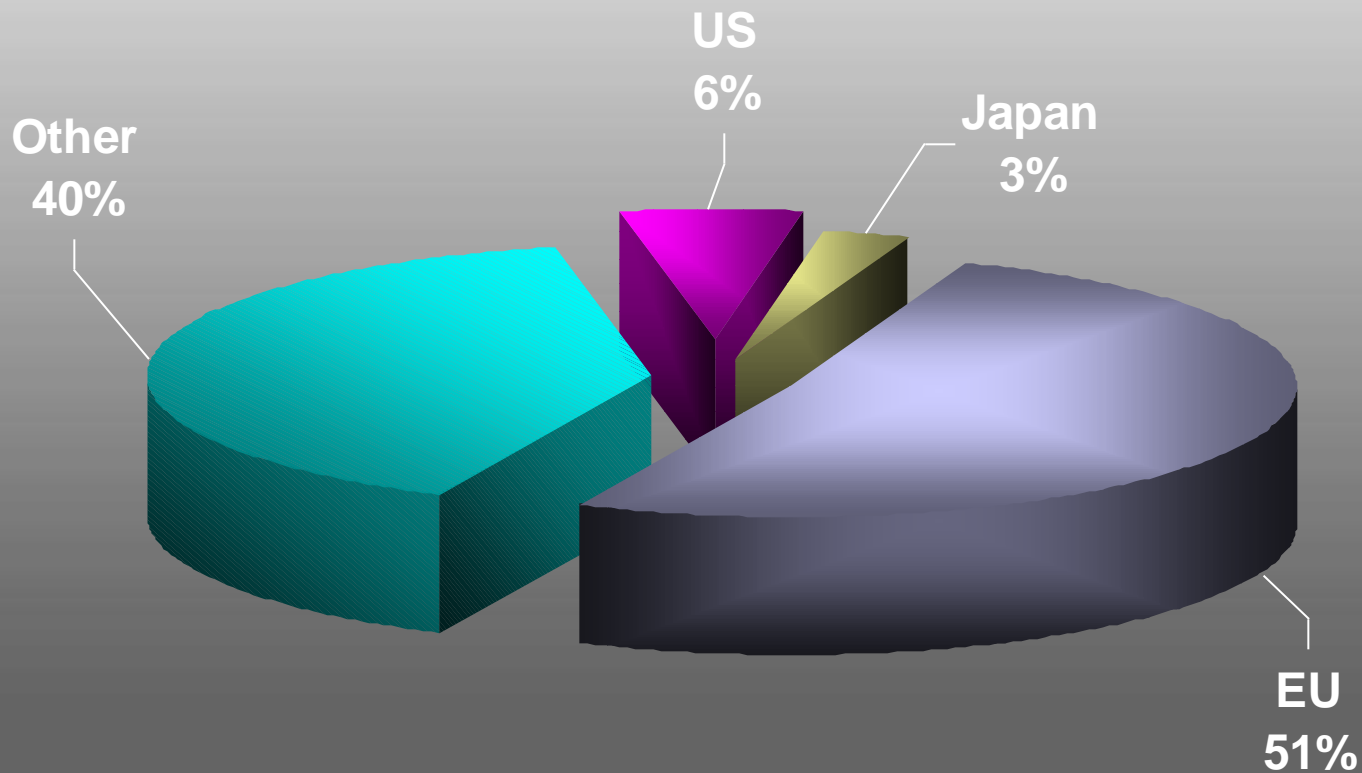


MedDRA Subscriptions by Level





Subscribing Regulators by ICH region





Subscribing Regulators

- Netherlands Anilles
- Argentina
- Austria
- Belgium
- Canada
- Switzerland
- Germany
- Denmark
- Estonia
- Finland
- France
- Greece
- Italy
- Lithuania
- Luxembourg
- Latvia
- Netherlands
- Norway
- New Zealand
- Poland
- Portugal
- Sweden
- Taiwan
- United Kingdom
- United States





User Group Objectives

- Discuss terminology issues
- Discuss policies and practices
- Identify issues that are important to subscribers
- Encourage communication among subscribers
- Encourage communication with the MSSO





Communications

- Subscribers to MSSO
 - MSSO web site comment page
 - Help Desk (877-258-8280)
 - Email - Mssohelp, Subscribe, Request
 - User Group Meetings
- MSSO to Subscribers
 - Web site postings
 - Newsletter “MedDRA Messenger”
 - Email broadcast messages
 - User Group Meetings





Web Site Utilization

- Policies and guidelines*
- MedDRA / ICH documents*- opportunity for comments available on Web
- Announcements (Meetings, Issues, Proposals, Training schedules, etc.)*
- Download consecutive data sets*
- Management Board abstracts
- Communication of translation information
- Proposed complex changes / conventions
- Communicate with the MSSO through the Web





MSSO Contract Changes

- Subscription level modifications
 - Basic
 - Restricted to non-profit, & government groups
 - System Developer
 - No change requests
 - Additional Core level
 - Core level 0 (new)
 - Core level 5





Additional Issues for SOC Review

- Finish review of Neoplasm SOC
- Review Swelling and Oedema
- Proposed use of NOS
- Review linking of Metastatic terms and Metastases terms
- Stabilization of database and reduction of number of internal maintenance changes





Summary of Changes MedDRA 5.0

<u>Changes</u>	<u>Number</u>
• New Terms Added	1574
• Terms Removed / merged	460
• Terms Renamed / modified	3596
• PT/LLT Terms promoted	169
• Primary SOC Reassigned	133





Summary of Changes MedDRA 5.0

Percentage of Terms Affected

- 0.00% of the SOCs
- 5.75% of the HLGTs
- 7.25% of the HLTs
- 11.50% of the PTs
- 9.12% of the LLTs





Summary of Changes HLGT Impact

- HLGTs
 - 4 HLGTs were added.
 - 5 HLGTs were removed / merged.
 - 9 HLGTs were modified / renamed.





Summary of Changes HLT Impact

- HLTs
 - 37 HLTs were added.
 - 39 HLTs were removed / merged.
 - 46 HLTs were modified / renamed.





Summary of Changes PT Impact

- PTs
 - 807 PTs were added
 - 416 PTs were removed / merged
 - 220 PTs were modified / renamed





Summary of Changes LLT Impact

- LLTs
 - 726 LLTs were added.
 - 2,816 LLTs were renamed / modified.
 - 169 LLTs were promoted

Note: includes internal review of naming conventions





Future Plans and Issues

- Web distribution of MedDRA
- Web distribution of translations
- Supplemental Terms
- ICD-10-CM mapping
- Coordination with NCI on CTC mapping





Increased MSSO Activities

- Advanced MedDRA Training
- CRA Training
- Implementation Support
- Data Conversion
- Increased Tool Suite
- Development of MedDRA CBT





Regulatory Mandate

- **Japan**
 - **Currently Accepted**
- **EU**
 - **1/1/2002 electronic ADR**
 - **1/1/2003 all reporting**
- **USA**
 - **Still in rule making process**
 - **Assumed similar to EU**





Status of MedDRA Translations

- MedDRA is currently available in English and Japanese
- EU has provided grant to respective countries to translate into French (completed 2001 to PT), German (completed 2000 to PT), Spanish (completed 2001 to LLT), Portuguese (completed 2001 to PT) to be delivered in March/April
- LLTs to be delivered when ready
- Greek completed to PT
- Dutch translations underdevelopment
- Danish and Italian planning stage





Next User Group Meeting

20 June 2002

Chicago, Illinois

38th Annual DIA Meeting

Visit the MSSO web site for details

www.meddramsso.com

