

JMO Overview

- Maintenance of MedDRA/J -

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Managing Director / JMO

Role of JMO

(Japanese Maintenance Organization)

- Partner to the MSSO for the Distribution of MedDRA in Japan
- Maintenance of MedDRA/J
- Participation in the International Medical Review

History of JMO & MedDRA/J

- 1998.9 JMO was established in the Society of Japanese Pharmacopoeia
- 1998.10 Survey was conducted to confirm the Practical Availability of MedDRA/J Draft
- 1999.3 First Official Version (ver2.1) of MedDRA/J was released
- 2000.9 MedDRA/J ver3.2 was released (updated quarterly)

SUBSCRIPTION

September 2000

Business type	Number of Subscribers
Pharmaceutical company	170
CRO	5
Hospital	10
Academia	10
Non profit Organization	3
Regulator	13
Other	20
Total	231

Services for Subscribers

Free Service

- Change Request
- Help Desk
- Browser
- Web Site
- User Group Meeting
- Quality Assurance

Change Request

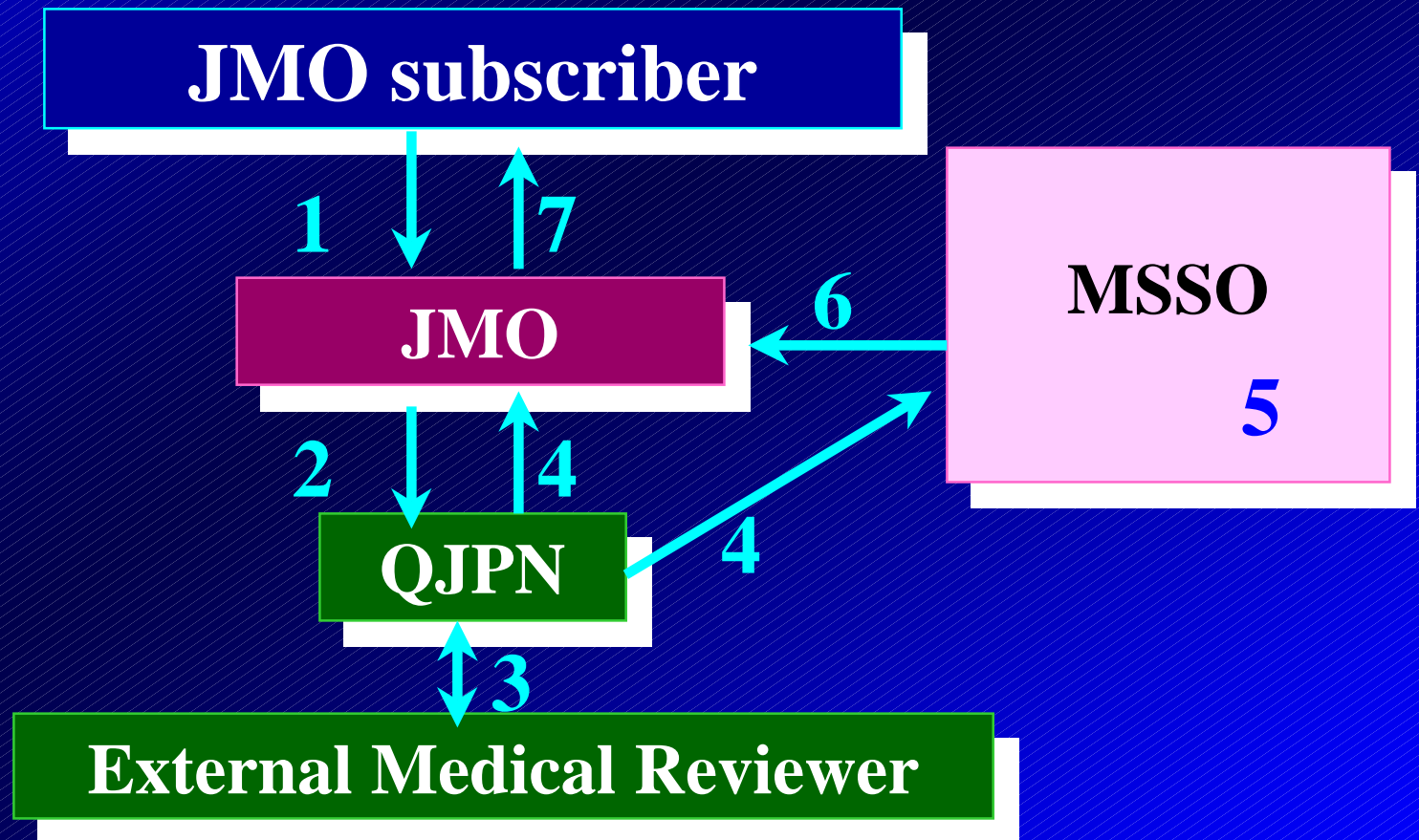
- Received 113 (10)
- Sent to MSSO 86

Help Desk

- Calls 203

As of September 30, 2000

MedDRA/J Change Request Flow Process (JMO subscribers → JMO)



User Group Meeting

	Date	Participants	Organization
MSSO/JMO	December 8, 1999	199	(83)
1st JMO	January 17, 2000	422	(140)
	January 20, 2000	147	(57)
2nd JMO	September 26, 2000	370	(125)
	September 28, 2000	145	(62)

Quality Assurance

- Cooperative System with JMO and QJPN
- SOPs of JMO and QJPN
- Specialized Medical Review Staff
- Participation in the International Medical Review
- Japanese Translation Evaluation from Medical Aspect

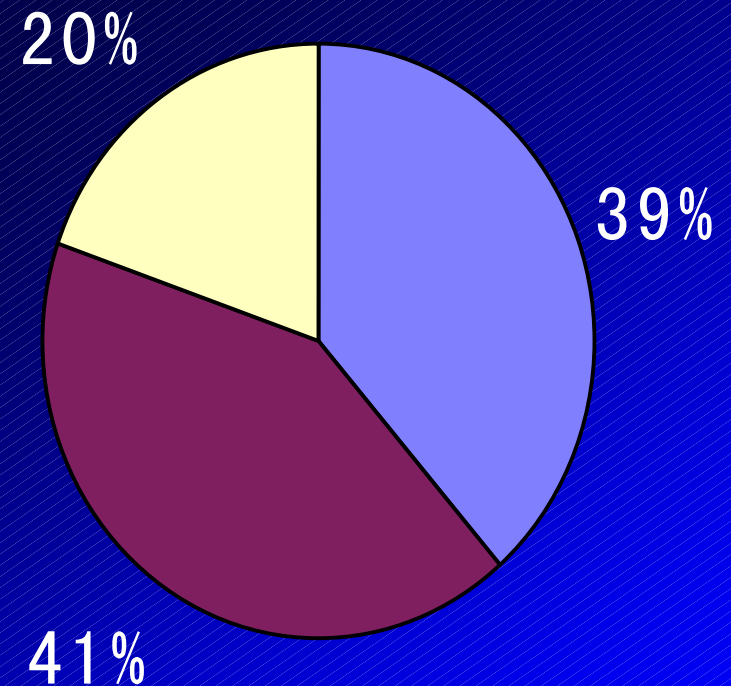
Questionnaire

September, 2000

- Sent out to all 231 JMO subscriber
- 149 replies (64.5 %)
- 132 replies from 170 Pharmaceutical companies (77.6 %)

Implementation of MedDRA/J

1. Implemented	51
2. Under examination	55
3. Not yet	26

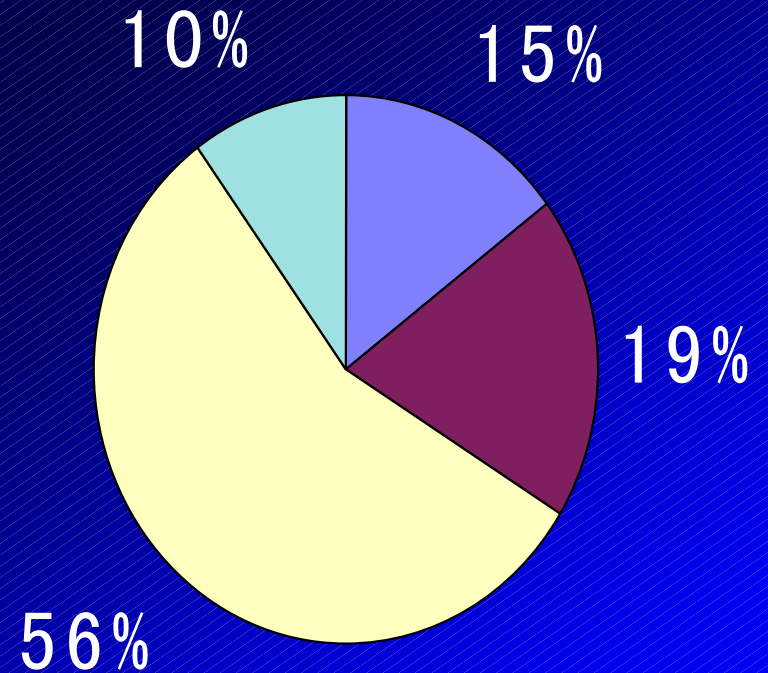


Objectives of Implementation

- | | |
|-------------------------------------|----|
| 1. Spontaneous report | 34 |
| 2. Post Market study | 10 |
| 3. Clinical study | 15 |
| 4. Legacy database migration | 6 |
| 5. Others (product information etc) | 20 |

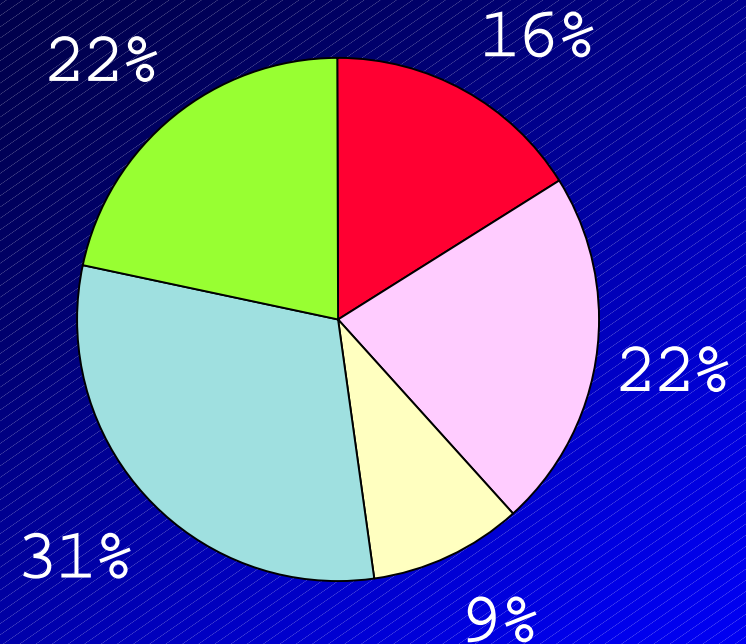
Regulatory Reporting

1. MedDRA/J	19
2. MedDRA/J, J-ART	25
3. J- ART	73
4. No report	13



International Exchange of Information

1.	MedDRA	21
2.	WHO- ART	29
3.	COSTART	12
4.	Others	40
5.	Not experienced	28



Next Step for the Future

- Training Seminar for Subscribers
- Strengthen Quality Assurance
- Other Service for Subscribers

Contact Information

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