



The WHO, WHAT, WHEN, WHERE, WHY and HOW of **MedDRA™** Implementation

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MedDRA™

MedDRA? is a trademark of the International Federation
of Pharmaceutical Manufacturers Association (IFPMA)



WHO is involved?

- IT
- Regulatory
- Drug Safety
- Clinical
- Labeling
- Legal
- Dictionary group
- Others??
- Don't forget... Upper Management (the "Big Bosses"!)



WHAT is involved?

- The mechanics – what are we embarking upon?
 - Legacy data
 - System preparation
 - Training
 - Maintenance



WHEN should we implement?

- Now?
- Later?
- What are the regulators thinking?
- Could we implement “too soon”? What if we implement “too late”?
- How long will the process take?



WHERE do we do this?

- Where are our “users”?
 - Centralized or decentralized?
- Training – off site/on site
 - Again, centralized or decentralized?



WHY?

- Why does our organization have to do this?
- What happens if we don't?
- What are the advantages of using MedDRA?
- Is there a downside?



Finally... HOW do we implement?

Let's share ideas –
MSSO is happy to help!