



# EU Pilot on E2B Submission

***MedDRA US user group meeting  
November 8, 2000  
San Diego***



# Status

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- 444 submissions including 1090 cases are submitted by June.
- Active participation.
  - Companies.
    - | MSD, Roche, Bayer vital, Astra Zeneca and Lundbeck.
  - Authorities.
    - | EMEA.



# Next step in the project

- Global communication using e-mail attachments and s-mime security/Templar/XMLbus
- Parallel FDA case exchange
- Future MHW participation



# Unique Case Identification

- Complexity of European reporting requires unique identification
- Elimination of redundant information
- One company - one identification
- Unique case identifier – company identifier + company number



# Use of XML suggested

- Several reports contain multilingual characters.
- Use of extended Latin character set is suggested
- XML contains character set information



# Translations

- LLT level problematic
  - Unique medical concepts
  - Always one English (American) LLT related ?
  - Always one PT related?
- MedDRA primarily translated to PT level
- Synchronisation of translated versions
- How to pay for the translations?
- Meeting between European regulators and MSSO is expected before next ICH meeting in May 2001



# MedDRA LLT versus PT

- LLTs for local translations
- PTs for unique medical concepts
- Use of codes as opposed to decodes. Facilitates individual mapping in local language
- Use of “reported term” as placeholder for LLTs



# Future

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- MedDRA and electronic submission suggested unanimously by the pilot group to be globally mandatory by 1. January 2003
- Possible use of XML to support local languages in Europe and globally
- Inclusion of FDA and MHW in global compliance testing
- Use of S-MIME e-mail suggested as global communication vehicle