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June 15-19, 2003

# San Antonio

*Henry B. Gonzalez Convention Center*



*Annual Meeting*



**2003 Chairperson**  
Murray M. Lumpkin, MD, MSc  
Principal Associate Commissioner  
U.S. Food and Drug Administration

[www.diahome.org](http://www.diahome.org)



# MedDRA<sup>®</sup> Initiatives: The Current and The Future

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# The Current Environment



# MedDRA Today Version 6.0

System Organ Class (26)

High Level Group Term (332)

High Level Term (1682)

*Special Search  
Categories (SSC)* →

Preferred Term (16,341)

Lowest Level Term (58,560)



## MedDRA Today (cont)

- Supplemental terms are posted every week
- Rejected terms are also posted with comments
- On going British and American spelling consistency efforts



# MedDRA's Translation Status

- MedDRA 6.0 is currently available in:
    - English
    - Japanese
    - Spanish completed to LLT level
    - German completed to PT level only \*
    - French completed to PT level only \*
    - Portuguese completed to PT level only \*
  - MedDRA 6.1
    - Dutch will be available to LLT level
- \* LLTs will be added in the future



# MedDRA Blue Ribbon Panel



Blue Ribbon Panel ~ 15 May 2003

To bring industry, regulators and interested parties together to discuss MedDRA and what the future plans are. Topics included:

- Growth of MedDRA
- Level of detail needed for data summarization
- Should medical device terms be included
- E2b



# MedDRA Blue Ribbon Panel

(cont)



Members of the Blue Ribbon Panel included representation from the three ICH regions, industry experts and MedDRA subscribers as observers

- Good representation
- A white paper to be written
- White paper will be available with the decisions and outcomes of the meetings

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# MedDRA's *Future Directions*





# Future Directions

CIOMS Advisory Panel and the MSSO cooperatively developed an analytical search tool for MedDRA which pools the efforts of CIOMS with SSQs and the MSSO with MAGs

these are now called

Standardized MedDRA Queries (SMQs)



## Future Directions (cont)

- SMQs are:
  - Intended to support the extraction of MedDRA coded data in a meaningful manner
  - Intended to support analysis and reporting
  - Similar to SSCs but may include any level of hierarchy and may include exclusion criteria
  - Parallel hierarchy to existing MedDRA structure



## Future Directions (cont)

- SMQs will address issues such as:
  - QT prolongation
  - Pancreatitis
  - Lactic acidosis
  - Stevens-Johnson syndrome
  - Hepatotoxicity
- Special Search Categories (SSC) will continue to be maintained



# Future Directions (cont)

- SMQs:
  - Are included as part of the MedDRA subscription
  - Initial SMQs to be provided in MedDRA 6.1
    - Anaphylaxis
    - Torsades de pointes/QT prolongation
    - Acute renal failure
    - Rhabdomyolysis
  - MSSO will work to develop new and different SMQs based on subscriber input and interest
  - Maintained with the terminology



# Future Directions (cont)

- ICD-10-CM mapping
  - Expected release 2004
  - Mapping will be a “cross-walk” table from ICD-10-CM to the most current version of MedDRA
  - ICD-10-CM terms will **not** be placed into MedDRA

# Future Directions (cont)



- MSSO expects to conduct future Blue Ribbon Panels
- MSSO is reviewing modified terms in MedDRA
  - A modifier is a term that can optionally be applied to a MedDRA term to modify the meaning
  - Aggravated, exacerbated, recurrent, acute, ...
- MSSO continues to get requests about adding new terms with modifiers
- MSSO needs to develop a policy about these terms



## Future Directions (cont)

- MSSO proposes to develop and produce a modifier file with MedDRA
  - Consists of a MedDRA code, term (e.g. aggravated) and MedDRA version
  - Distributed with terminology at no additional cost
  - Can be optionally used in conjunction with any existing MedDRA term at the users discretion
  - Lessens the need for adding new terms to MedDRA
  - Open to change requests



## Future Directions (cont)

- Next steps for MSSO modifier proposal:
  - Produce draft file format
  - Post for subscriber comment
  - Management Board and subscriber approval for production
  - Revise concept based on comments
  - Update/expand existing documentation to include modifiers



# MedDRA 6.1

- Release scheduled for 1 September 2003
- Changes in the 6.1 release include:
  - NOS terms will be demoted to the LLT from the PT level
  - SMQs will be added
  - Dutch translation will be available



# Users *Future* in MedDRA

- Be informed
  - Attend MedDRA user group meetings
  - Monitor websites for review and comment on documents
  - Participate in industry groups
  - Participate in regulatory pilots



# Next User Group Meeting

US User Group Meeting  
San Antonio, Texas  
19 June 2003

1pm – 4pm

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DIA Annual Meeting



Questions?

[www.meddramsso.com](http://www.meddramsso.com)