



*MedDRA: an Update
from the FDA*



MedDRA User's Group
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Presentation Outline



- Brief history
- Upversioning history
- E-sub status and implications
- MedDRA as a reporting requirement
- Development of HHS-wide standards
- HHS - CAP agreement on SNOMED
- Questions

MedDRA Implementation: History



- November 1997: began using MedDRA in AERS
- Migrated 1.5 million records from SRS
 - COSTART to MedDRA mapping
 - MedDRA version 1.9
- Approximately 1.5 million reports coded since November 1997
 - MedDRA Preferred Terms

MedDRA Upversioning: History



- 1.9 to 4.0: Dec 2001
- 4.0 to 6.0: May 2003
- to 6.1: Jan 2004
- to 7.0: May 2004
- slated for 7.1 November 2004

AERS Submissions in MedDRA

- Expedited electronic reporting initiated August 2000
- 8 US companies submitting
- Over 75,000 case reports received to date, many pre-coded in MedDRA
- Processing e-submissions less costly than paper submissions

AERS Submissions in MedDRA

- E-subs accepted using either MedDRA text string or MedDRA numeric code
- Paper reports: Narrative as basis for coding into MedDRA
- E-subs:
 - narrative as basis for Quality Control
 - recoded when MedDRA versions are discrepant or coding quality is unacceptable

Evaluation of Industry's Submissions Coded in MedDRA

- Evaluation plan developed by AERS Coding Working Group, with oversight by the OPaSS
- Statistically valid sampling plan developed by the Office of Biostatistics
- PSI Coders perform evaluations under existing coding contract

Evaluation of Industry's Submissions Coded in MedDRA

- Criteria for unacceptable errors
 - missed medical concepts
 - “soft coding” - a company reports the event but codes it with a term of less severity /specificity
- Downsampling to maximize effectiveness of QC review resources

E-Sub / MedDRA Companies

<u>Company</u>	<u>E-sub Date</u>	<u>MedDRA Date</u>
Merck	Aug 2000	May 2002
Roche	Sept 2000	Mar 2001
GlaxoSmithKline	Oct 2000	May 2002
Bristol-Myers Squibb	Sept 2001	Nov 2001
Aventis	July 2003	July 2003
Novartis	July 2003	July 2003
Amgen	April 2004	April 2004
J & J	May 2004	May 2004

Proposed Rule: Safety Reporting Requirements for Human Drug and Biological Products

- Published March 14, 2003
- Comment period closed October 14
- All comments public and available for review through the docket 00N-1484

MedDRA in the Proposed Rule

- Code each SADR at PT level for Individual Case Safety Reports
- Same for any SADRs associated with a Medication Error
- Intention to grant waivers on MedDRA requirement for small companies, on a case-by-case basis

*SADR = Suspected Adverse Drug Reaction

Comments to Proposed Rule Regarding MedDRA

- FDA received 109 unique comments regarding the proposed rule; many addressed the MedDRA requirement
- FDA reviewing the comments and considering them as the final rule is prepared

*Development of HHS-wide
Standards*



President's e-Gov Initiative

- Consolidated Health Informatics (CHI)
 - an Office of Management and Budget e-Gov initiative led by the Centers for Medicare & Medicaid Services
 - Scope: to establish a portfolio of existing clinical vocabularies and messaging standards enabling federal agencies to build interoperable federal health data systems

Health Level 7 (HL7)

- An accredited, ANSI standard organization that produces the HL7 messaging standard for communicating clinical data.
- HL7 standard is supported by every major medical informatics system vendor in the US.

Health Level 7 Mission

- To provide standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems.

HL7 Messaging Standard

- Hospitals use HL7 for laboratory orders, billing requests, pharmacy orders, medical records and a number of other applications. FDA wants to receive voluntary adverse event reports electronically from these healthcare institutions in what will be an HL7-approved format of an E2B information subset (as currently sent on a FDA 3500 MedWatch form).

HL7 RCRIM Technical Committee



- RCRIM = Regulated Clinical Research Information Management
- HL7 RCRIM TC formed as a collaboration of CDISC, FDA, HL7
- Industry participation central to process

HL7 RCRIM Technical Committee

- To facilitate the development of common standards for clinical research information management across a variety of organizations -- including government agencies (FDA, CDC, NIH), private research efforts, and sponsored research -- and thus the availability of safe and effective therapies by improving the processes and efficiencies associated with regulated clinical research.

Clinical Data Interchange Standards Consortium



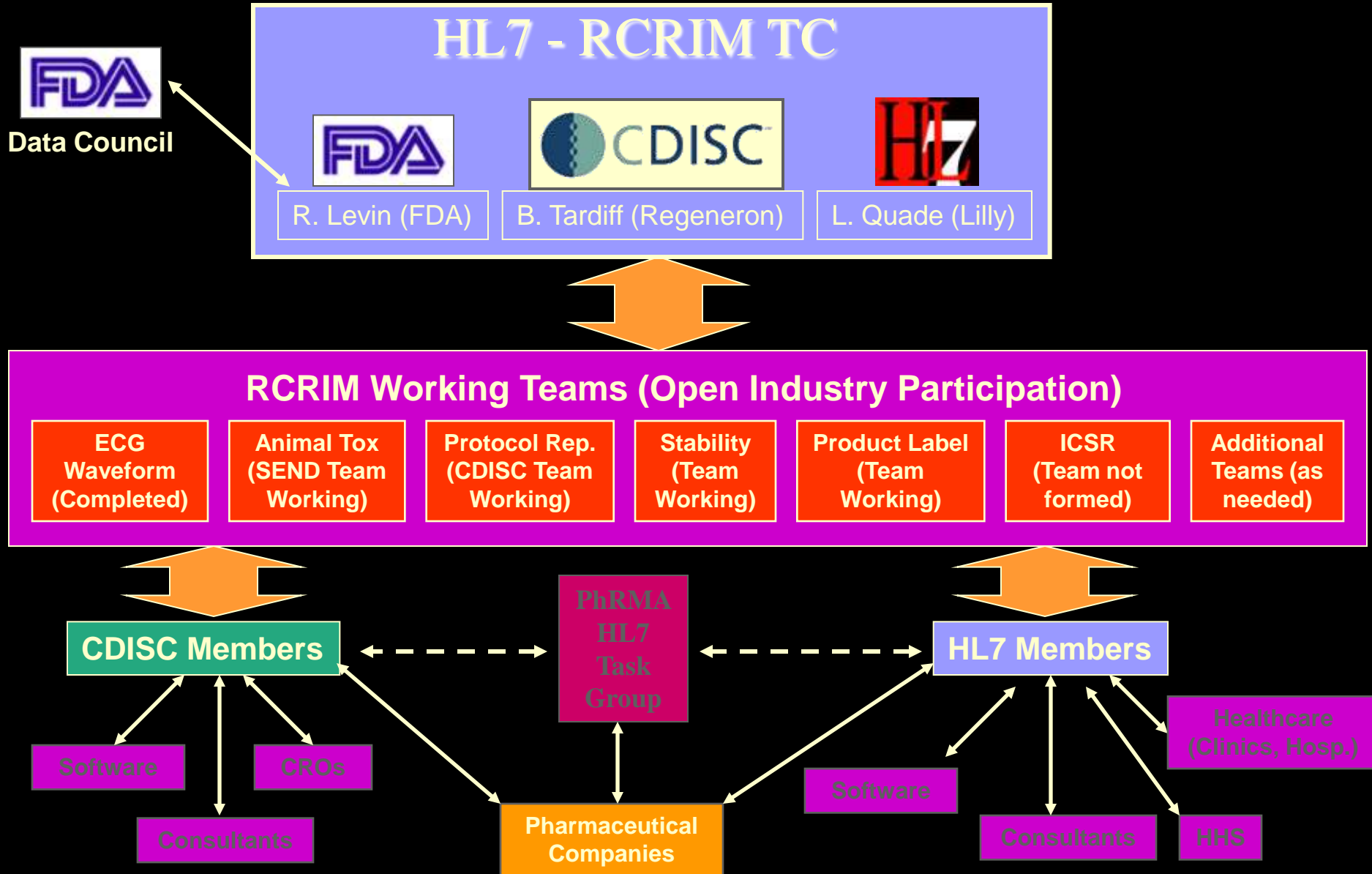
- CDISC is an open, multidisciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development.

Clinical Data Interchange Standards Consortium



- The mission of CDISC is to lead the development of global, vendor-neutral, platform independent standards to improve data quality and accelerate product development in our industry.

HL7 RCRIM: Organizational Diagram



HHS Supports SNOMED CT for Electronic Patient Medical Record

- 5-yr \$32.5 million agreement between HHS and the SNOMED organization
- New CHI standards include 5 for SNOMED: laboratory result contents, non-lab interventions and procedures, anatomy, diagnosis and problems, nursing.
- SNOMED CT available at no charge to users; can download from the NLM as of May 6, 2004

HHS Supports SNOMED CT for Electronic Patient Medical Record

- VA, DoD, CDC implementation of SNOMED underway for ePMR
- Possible that voluntary Adverse Drug Reaction reports will be received by FDA encoded in SNOMED

SNOMED Evaluation at FDA

- FDA needs to figure out how to work in dual environment
- Prior to 7/1/03 HHS-CAP agreement, very little awareness about SNOMED at FDA
- Formed SNOMED Evaluation Working Group in September (CDER, CBER, CDRH, CFSAN)



Goal

Compare SNOMED to MedDRA in
premarketing and postmarketing
activities



Plan

- Use a sample of real Adverse Drug Reaction reports to compare SNOMED to MedDRA for report coding and for retrieval and signal detection
- Assess impact on data mining
- Get idea of impact on use in CAERS, VAERS, AERS

Problems Encountered

- Unable to effectively access the terminology
- (However, SNOMED CT newly available - May 6 - through NLM's UMLS)
- Need basic SNOMED training

Problems Encountered

- Lack of experienced SNOMED users, especially with respect to data output aspects
- Need tools to facilitate evaluation
- Need validated mapping between MedDRA and SNOMED

Moving Forward with MedDRA

- Jan. 29, 2004 letter from NCVHS to Secretary Thompson:
 - “...it is essential that accurate mappings exist between SNOMED-CT and other administrative code sets and terminologies including ICD-9/10-CM, DSM (Mental Health) and MedDRA (Adverse Event Reporting). Consistent with NCVHS recent recommendations, mapping needs are being referred to the National Library of Medicine.”

Moving Forward with MedDRA

- Working group efforts may resume following availability of mapping
- Watching other agencies and organizations
- Possibility of collaborating on an evaluative project with NCI and NIH, which would provide 2nd level of testing for the new mapping

Moving Forward with MedDRA

- FDA would like to learn if there are organizations that have experience in using SNOMED for recording information related to either adverse events or clinical trials associated with medical products
- Potential for collaboration
- Datasets to enable conduct of 2nd level of testing for the new mapping

Moving Forward with MedDRA



- Expect the resolution of mapping issues will take some time
- First draft of mapping available from AHRQ in about a month
- Timeline for initial stage of testing the mapping has not yet been determined

QUESTIONS ???

