

Data Mining

Status of FDA's Efforts

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Background

- **Cooperative Research and Development Agreement (CRADA)**
 - FDA and Lincoln Technologies
 - Purpose: to develop data mining software (WebVDME)
 - March 2003 - July 2005
- **Decision made to put WebVDME into production**

The Year In Review...

- **Many tasks needed to prepare for production**
 - **System Development Lifecycle (IT) obligations**
 - **User Acceptance Testing**
 - **User training**
 - **Contract negotiation, award**

Production Use

- **WebVDME 5.1 now available for use by all safety evaluators, epidemiologists in CDER's Division of Drug Risk Evaluation (DDRE)**
- **Strengthens and complements existing pharmacovigilance tools**
 - **Exact details of use still being worked out**

Future Directions

- **Expanded application**
 - medication error surveillance
 - assessment of safety in clinical trials
 - signal detection in electronic longitudinal medical records, claims data
- **Research**
 - enhanced methods (e.g., assessing the role of polypharmacy in adverse events)