

Post-Market Drug Safety: Current Initiatives & Future Directions

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Presentation Overview

- Program Review
- Current Efforts to Strengthen Surveillance/Safety Assessment
- Future Directions





Post-Marketing Risk Assessment Program

- Primary roles:
 - Tracking adverse events of marketed drugs (note: includes medication errors)
 - Monitoring the utilization of marketed drugs
 - Soliciting/performing population-based epidemiologic studies





Post-Marketing Risk Assessment Program (cont'd)

• Expanding/evolving roles:

- Pre-marketing safety assessment
 - reviewer's template
 - pre-approval safety conferences
- Medication error prevention (names, packaging)
- Pharmacovigilance planning
 - ICH E2E guidance





Post-Marketing Risk Assessment Program (cont'd)

• Expanding/evolving roles:

- Risk minimization action plans (RiskMAPs)
 - greater focus of staff, interactions with review divisions
- Risk communication
 - MedWatch
 - list serve and partners
 - patient information
 - consumer medication information
 - emerging issues





Current Initiatives

- Voluntary Reporting
- Improved Surveillance
- Access to Population-based Data
- Strengthening Internal Processes



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Current Initiatives - Voluntary Reporting

Adverse Event Reporting System

- Improvements
 - what we get
 - how we get it
 - how we use it
 - how we make it accessible





Voluntary Reporting (cont'd)

- Improve quality of reporting
 - "Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment"
 - good reporting practice
 - characteristics of a good case report
- Make reporting easier
 - For HCP/consumer
 - web-fillable, interactive, "push a button to populate a MedWatch form and submit to the FDA"
 - For industry
 - electronic reporting, more timely receipt and efficient processing of data, rulemaking



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Voluntary Reporting (cont'd)

Get more out of data

- 3 million reports in AERS, 420,000+/year
- Analytic tools (e.g., data mining)
- Make it more accessible
 - Emerging issues
 - NTIS quarterly abstract available on website
 - http://www.fda.gov/cder/aers/extract.htm
 - AERS 2 in development for '07-'08





Current Initiatives - Surveillance

- Purposeful ("active") surveillance
 - NEISS-CADES
 - DILIN
 - DAWN
 - Request for Information
 - Database linkage
 - administrative
 - pharmacy
 - clinical (i.e., electronic medical record)
 - examples CMS, HMO





Current Initiatives Population-based Data

- Access to broader range
 - Population-based studies
 - currently evaluating RFP submissions
 - indirect access to US claims databases
 - GPRD
 - Linked databases
 - support studies as well as surveillance, e.g. CMS
 - methods development



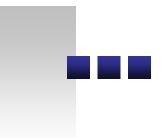


Current Initiatives Internal Processes

- Accountability
 - Over 1,300 reviews a year
 - Tracking recommendations
- Communication
 - Pre-approval safety conferences
 - Risk management
 - Routine face-to-face on high priority issues
- Process Improvement Teams







Future Directions...





Future Directions - I

Science of safety

- Mechanistic understanding of drug injury processes
- Population variability, who is at risk
- Treatment "empirical" and assessment "circumstantial" until we have markers for drug-induced injury
- Better pre- and post-market assessment





Future Directions - II

- Enhanced clinical assessment methods
 - Pre- and post-market
 - Improved trial design
 - enrichment, adaptive designs
 - better utilization of existing data
 - Robust post-marketing assessment program





Future Directions - III

- Strengthen the post-marketing toolkit
 - AE/ME reporting
 - Drug utilization databases
 - "Active" surveillance
 - US claims-based health encounter data (indirect access) - methods development





Future Directions - IV

Strengthening CDER

- Staffing for enlarging mandate
 - review and evaluation of risk minimization action plans
- Improve internal processes
 - work processes, roles/responsibilities
 - communication
 - information flow
 - tracking and accountability
 - priority setting





Future Directions - V

- Strengthening Partnerships
 - Federal agencies
 - CMS, AHRQ, CDC, NIH, HRSA
 - Academia
 - CERTs
 - Healthcare institutions
 - payers, providers
 - Sponsors
 - pre- and post-marketing responsibilities



5



Future Directions -VI

Effective communication

- Improve therapeutics
 - realizing benefits
 - minimizing risks
- Enhance patient safety
- Reduce medication errors
- Healthcare system issue





DSaRM AC Meeting May 18-19, 2005

- Explore issues related to FDA's risk assessment program for marketed drugs
 - Advantages, disadvantages of current system
 - Ways to improve current system
- Outcomes
 - Current passive system good for detecting rare, serious events with short latency periods
 - Develop external relationships/alliances
 - Need for adequate funding
 - Need for additional research





- Detecting, assessing, managing, communicating the risks and benefits of drugs is complex and demanding
- Number of initiatives, planned and ongoing, aimed at improving postmarketing risk assessment



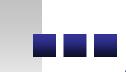


Conclusions (cont'd)

- Post-marketing period should be considered an equally important phase of drug development
- Broaden lifecycle approach to development and monitoring











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