Pharmacovigilance using Large Healthcare System Databases

IOM Symposium on the Future of Drug Safety
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IOM Recommendations
Session 3: Enhancing Post Market Safety Monitoring

4.1: The committee recommends that in order to improve the generation of new safety signals and hypotheses, CDER (a) conduct a systematic, scientific review of the AERS system , (b) identify and implement changes in key factors that could lead to a more efficient system, and (c) systematically implement statistical-surveillance methods on a regular and routine basis for the automated generation of new safety signals.

4.2: The committee recommends that in order to facilitate the formulation and testing of drug safety hypotheses, CDER (a) increase their intramural and extramural programs that access and study data from large automated healthcare databases and (b) include in these programs studies on drug utilization patterns and background incidence rates for adverse events of interest, and (c) develop and implement active surveillance of specific drugs and diseases as needed in a variety of settings.

4.6: The committee recommends that CDER build internal epidemiologic and informatics capacity in order to improve the postmarket assessment of drugs.

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Surveillance System capability

- Focus on the period of uncertainty
- Be capable of finding
  - Classic “drug list” events
  - Drug or class specific suspected events
  - Increases in events with large public health consequences
  - Unsuspected events
- Assay benefit
- Be a source for validating signals through hypothesis testing observational studies
- Operating chacteristics
  - Quantitative
  - Longitudinal
  - Near real time monitoring

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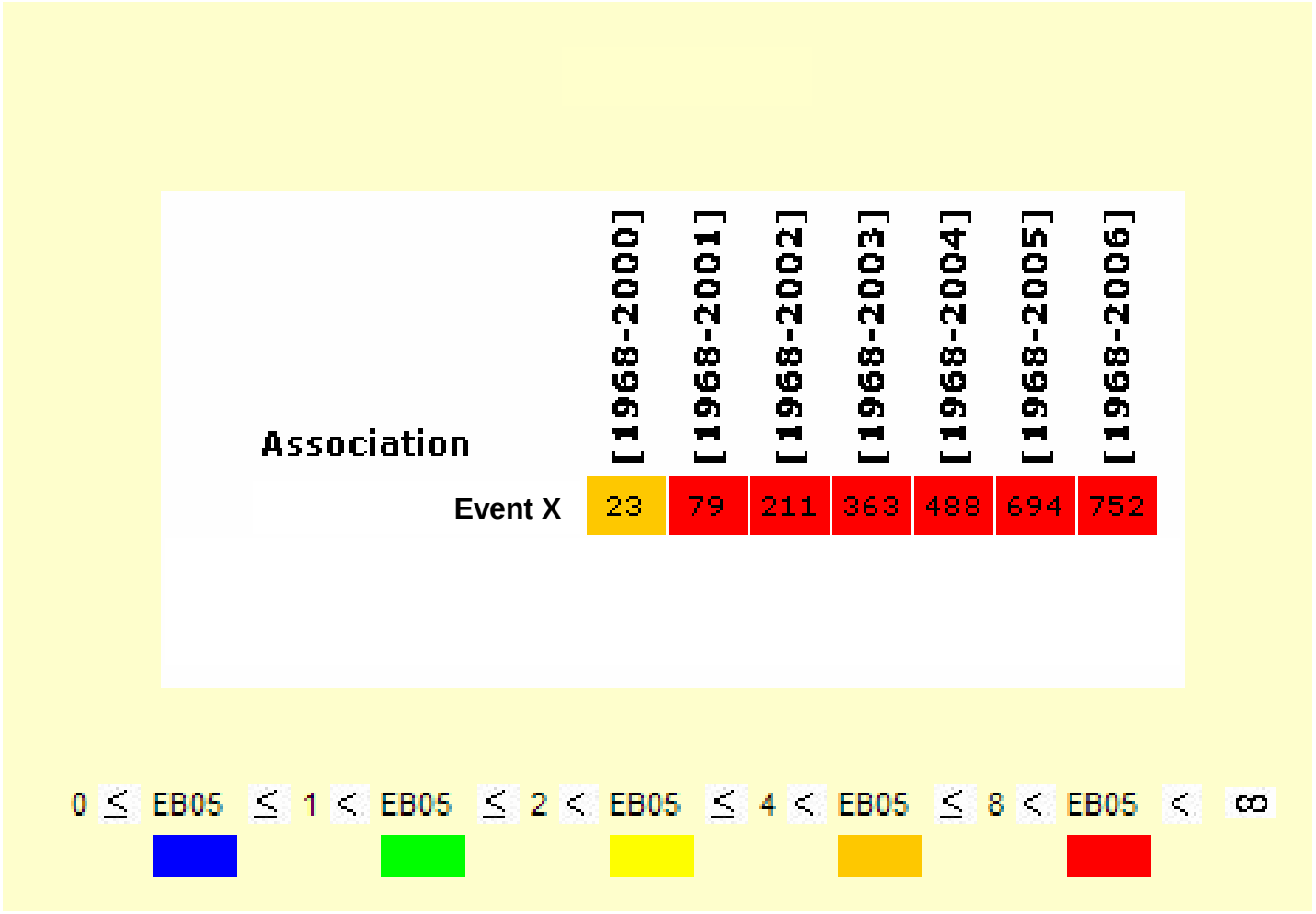
GSK analysis

- Data sources
  - Insurance claims: Integrated Healthcare Information System (IHCIS), ~40 million lives, 22 months exposure
  - Electronic medical records: GE Medical, ~5 million lives, 22 months exposure

- Developed methodology
  - Ontologies to identify same events in multiple databases
  - Identify temporal relations
    - Symptoms and Diagnoses after prescription: drug-condition pairs
  - Perform internal validation

Disproportionality analysis of event X in the AERS database



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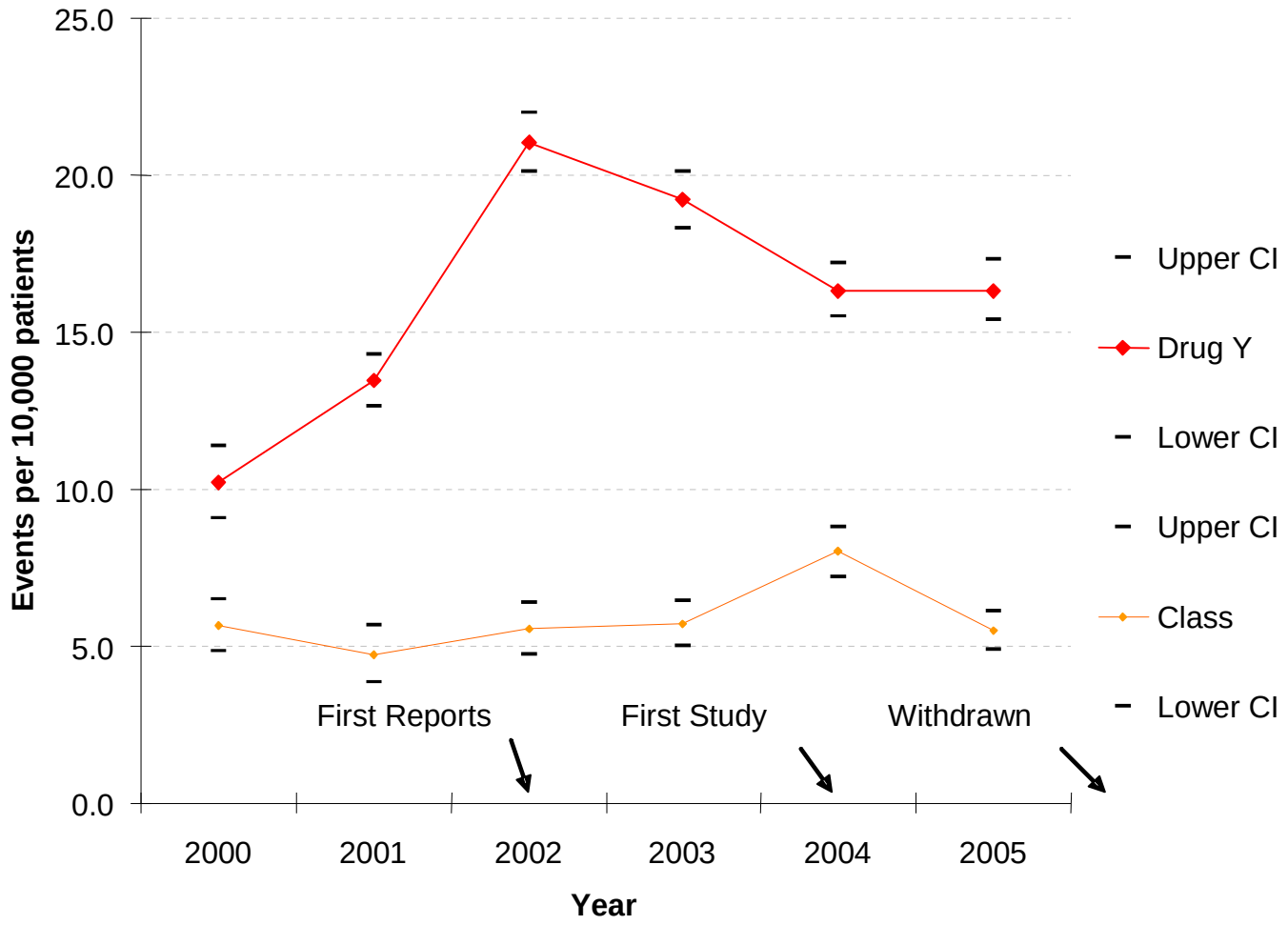
Rates of Event X using Observational Data



Surveillance System requirements

- Data
- Accepted methodology
- Resources
  - People
  - Expertise
  - Money
- Rules and procedures
- Governance

Public Private Partnership Model

- Accept public and private funds
- Governance includes representatives of all stakeholders
- Entity:
  - Acquires data
  - Develops and agrees best practice methodology
  - Conducts analyses
  - Reports Results
- Interpretation is the province of FDA & Sponsor
- FDA has authoritative access

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