Exponent®

FDA Sentinel Network

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Marta Villarraga, PhD
Duane Steffey, PhD

Contributors:

Jordana Schmier, MA
Edmund Lau, MS
Tack Lam, MD, PhD
Rose Ray, PhD
Michael Kelsh, PhD
Jill Card, MS
Wai Chan, PhD
Steven Kurtz, PhD

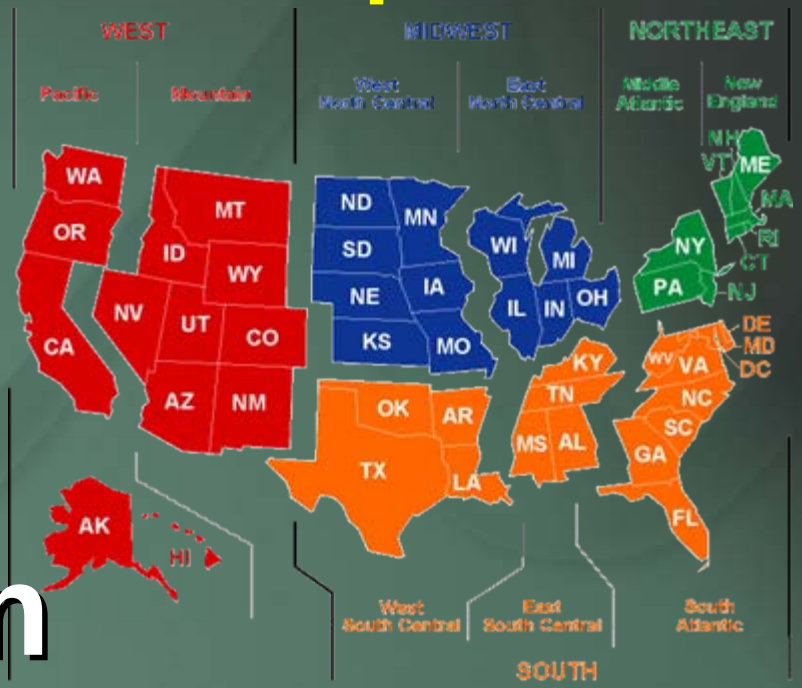
Exponent®

Exponent Expertise

- Failure analysis of medical products
- Development, maintenance, and use of large, electronic, population-based databases for risk analyses
- Risk identification and risk analysis methodologies
- Risk communication

Sentinel Network

- Surveillance
- Assessment
- Communication



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Surveillance

GAPS:

- Consistency in data collection and coding for harmonization (ISO 14971)
- Information on successful products, unreturned products, and total exposure
- Incentive and feedback for voluntary reporting

CONSIDERATIONS:

- Adaptive, automated, advanced control systems to handle complex health care delivery and reporting processes
- Usability evaluation of data collection systems for compliance at point of care

Assessment

GAPS:

- Automatic linking of common reports
- Inability to compare across devices
- Effects of confounding variables
- Frequentist statistical methods may be ill-suited for recurring analyses or complex modeling
- Definition of “reasonable risk”

CONSIDERATIONS:

- Propensity scores for risk adjustment
- Bayesian inference and decision analysis
- Dynamic statistical models (e.g., neural networks)
- Interaction of industry, FDA, and independent panels of experts

Questions 6, 7

Communication

GAPS:

- When to notify of adverse event(s)?
- What to communicate to which constituents?
- Impact on patients and providers?
- What is the best format?

CONSIDERATIONS:

- Completeness of information
- Data limitations
- Putting risk into perspective
- Health care surveillance loops
- Interaction of industry, FDA, and independent panels of experts

Selected Publications

- Villarraga M, Most E, Kurtz SM. *Risk communication of medical device failures.* Update *(FDLI).* September/October 2004.
- Kelsh MA, Buffler PA, Daaboul JJ, Rutherford GW, Lau EC, Barnard JC, Exuzides AK, Madl AK, Palmer LG, Lorey FW. *Primary congenital hypothyroidism, newborn thyroid function, and environmental perchlorate exposure among residents of a Southern California community.* J Occup Environ Med 2003;45(10):1116-27.
- Moore TL, Vijayakumar V, Steffey DL, Ramachandran K, Corrigan CF. *Biomechanical factors and injury risk in high-severity rollovers.* Annu Proc Assoc Adv Automot Med. 2005;49:129-46.
- Schmier JK, Kane DW, Halpern MT. *Practical applications of usability theory to electronic data collection for clinical trials*. Contemporary Clinical Trials 2005; 26(3):376–385.
- Tarter ME, Lock MD, and Ray RM. *Conditional switching: A new variety of regression with many potential environmental applications*. Environmental Health Perspectives 1995;103(7–8):748-755.