

The Future of Drug Safety – Challenges for FDA. Session 3: Enhancing Post Market Safety Monitoring

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Safety System



Session 3 Objectives

- IOM Recommendations
- FDA's Capacity and Initiatives
- Use of Existing Resources
- Need for Additional Resources



Introductions of Panelists

- Gerald Dal Pan
- Mark McClellan
- Richard Platt
- Barbara Alving
- Alec Walker
- Ron Krall



Postulate

Major components of drug safety assessment:

- Generation of hypotheses from safety signals
- Strengthening of safety signals
- Conduct of confirmatory studies
- Evaluation of risk management programs
- Continuing systematic evaluation of risks and benefits



Recommendations

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) implement statistical-surveillance methods for the automated generation of new safety signals.



Recommendations

4.2: The committee recommends that in order to strengthen and test drug safety hypotheses, CDER should (a) increase their intramural and extramural programs that can access and study data from large automated 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 for specific drugs.



Recommendations

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



The Future of Drug Safety – Challenges for FDA. Session 4: Conducting Confirmatory Drug Safety and Efficacy Studies

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Session 4 Objectives

- IOM Recommendations
- FDA's Capacity and Initiatives
- Use of Existing Resources
- Need for Additional Resources



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Introductions of Panelists

- Janet Woodcock
- Robert Califf
- Deborah Zarin
- Gretchen Dieck



Recommendations

4.3: The committee recommends that the Secretary of HHS, working with the Secretaries of Veterans Affairs and Defense, develop a public-private partnership with drug sponsors, public and private insurers, for profit and not for profit health care provider organizations, consumer groups, and large pharmaceutical companies to prioritize, plan, and organize funding for confirmatory drug safety and efficacy studies of public health importance. Congress should capitalize the public share of this partnership.



Recommendations

4.11: To ensure that trial registration is mandatory, systematic, standardized, and complete, and that the registration site is able to accommodate the reporting of trial results, the committee recommends that Congress require industry sponsors to register in a timely manner at clinicaltrials.gov, at a minimum, all Phase 2 through 4 clinical trials, wherever they may have been conducted, if data from the trials are intended to be submitted to the FDA as part of an NDA, sNDA, or to fulfill a postmarket commitment. The committee further recommends that this requirement include the posting of a structured field summary of the efficacy and safety results of the studies.

