Evidence-Based Decision Making In Healthcare

Post-Marketing Surveillance

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Phase 4 Trials

- After drug approved, sold on market
- Long-term safety
  - Adverse events
  - Drug-drug interactions
- Long-term efficacy
- Findings can lead to FDA taking action

MedWatch

- Not a “trial,” but a system to collect data
- Covers
  - Prescription, over-the-counter, biologic medicines
  - Medical devices
  - Special nutritional products, supplements & infant
  - Cosmetics such as moisturizers, makeup, shampoos
  - Food, such as beverages and food additives

MedWatch Online Voluntary Reporting Form

Welcome

If this is a medical emergency, please call 911.
If you have a mental health crisis, please call 988.

Health professionals, consumers and patients can voluntarily report observed or suspected adverse events for human medical products t FDA. Voluntary reporting can help FDA identify unknown risk for approved medical products. Reporting can be done through our onlin reporting portal or by downloading, completing and then submitting FDA Form 3500 (Health Professional) or 3500B (Consumer/Patient) t MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

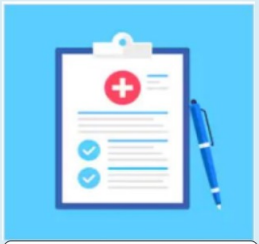
While not mandatory, FDA encourages reporters to provide their contact information in case FDA needs to gather more information. Not that reporters can request, within the report, FDA not release their contact information to the manufacturer.

Begin Online Report

Health Professional
(FDA Form 3500)

Consumer/Patient
(FDA Form 3500B)

En español para el consumidor / paciente (formulario 3500B de la FDA)



Continue an incomplete report

Click here to continue filling out an incomplete report. You will need Report ID and Report Date. You will have 3 days to complete this report from the start date.

How MedWatch Works

- Provider or patient submits Form 3500B
- An FDA safety evaluator reviews report and examines database for similar reports
- FDA monitors the data for trends and investigates, if appropriate

Potential FDA Actions

- Safety alerts with recommendations to monitor a product's use, adjust the way it is used, or stop using it
- Updating the product labeling to reflect new warnings
- Inspecting the manufacturer
- Requesting a change in the product’s design, manufacturing process, packaging, or distribution
- Requesting that a company recall a product

Weaknesses

- Under-reporting: relies on healthcare providers and patients to report
- Reactive: adverse events must occur before action
- Expensive to conduct without a strong economic incentive to perform

Potential Improvements

- ”Big Data” approaches to collecting and analyzing data from pharmacies, electronic health records, patients
- Promote public and provider awareness and reporting of need for reporting adverse events
- Funding and infrastructure for CDC, FDA, and/or academic centers to conduct post-marketing surveillance and report results in “real-time”