

VHA's Adverse Drug Event Reporting Program

Postmarketing drug surveillance is vital to reporting adverse drug events (ADE) to the FDA and VHA. A cornerstone of this approach is the collection and evaluation of reports of ADEs through voluntary reporting by healthcare professionals. The safety profile of a drug evolves over time as new information is discovered on a drug with its use in larger populations and subgroups not previously studied during clinical trials. ADE reports contribute to drug safety by triggering signals of potential problems that may lead to heightened awareness of drug reactions and further promote interdisciplinary problem solving of the drug's safety and attributes between pharmacists, physicians, nurses and other healthcare professionals.

VHA has developed an integrated web-based application that fully automates the VA's adverse drug event (ADE) reporting process (including direct submission to the FDA's MedWatch program) through a single portal for all VA facilities. This system is called the VA Adverse Drug Event Reporting System (VA ADERS) and can be accessed at <https://medora.va.gov/adr>. With ADE searches being facilitated by the modernized web-based interface technology developed by the VA, VA ADERS will have the capability to extract desired ADE information by standardizing how the data submitted to the system is coded. VA ADERS will also increase VAMCs report capability to detect ADEs of clinical significance and ability to download consolidated reports on suspect drugs.