A major milestone towards a nationwide electronic medical product safety system

FDA's "Mini-Sentinel" safety pilot program is up and running, demonstrating rapid analysis of medical product safety questions

FDA's "Mini-Sentinel" pilot program, the Agency's first step towards building a nationwide rapid-response electronic safety surveillance system for drugs and other medical products (which will be called the Sentinel System), is now up and running, enabling scientists to evaluate safety questions far more rapidly than using traditional channels.

Mini-Sentinel at-a-glance

- 99 million individuals
- 2.9 billion prescription drug dispensings
- 2.4 billion unique medical encounters, including 38 million acute inpatient hospital stays

In actuality, the Mini-Sentinel database is not so "mini"; the pilot project, which took two years to develop, includes 17 data partners across the U.S., and encompasses the data of nearly *100 million patients*. Mini-Sentinel evaluations will help scientists better understand potential safety issues associated with FDA-approved medical products. Importantly, scientists can get responses to their questions in a matter of weeks, as compared to months, or even longer using traditional surveillance methods.

Initial results of the Mini-Sentinel program's data analysis capabilities were presented by FDA's lead Sentinel scientist, Dr. Judy Racoosin and the Mini-Sentinel Lead from Harvard Pilgrim Health Care, Dr. Richard Platt, at the International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) held August 14-17, 2011 in Chicago.

For more information, visit the Mini-Sentinel website at http://mini-sentinel.org/.