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FDA updates MDR program in an effort to increase transparency

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FDA recently announced new changes it is making to the Medical Device Reporting (MDR) program as part of its ongoing efforts to increase transparency on device performance, and detection of device-related safety concerns.

FDA is formally discontinuing the Alternative Summary Reporting (ASR) Program, which permitted certain device manufacturers to file quarterly reports rather than individual reports. All data submitted under the program are available on the MDR Data Files web page.

The ASR data is available only in compressed files containing data for one year.

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Starting in 2017, the ASR Program also required manufacturers to submit a "companion" medical device report for visibility through the Manufacturer and User Facility Device Experience (MAUDE) database so the most recent files are searchable. For the years 1999 to 2016, the data are available, but not easy to navigate.

Files from CDRH's Device Experience Network (DEN) also are available on the MDR Data Files page. These include files from the database that pre-dates the MAUDE database.

Like the ASR data, DEN data are available in compressed, downloadable files containing data by year, but the DEN files also can be searched by product description, product code, manufacturer and report type.

FDA also provided an update on its plans to make the MAUDE database more user friendly and for active surveillance using the National Evaluation System for health Technology (NEST).

While improving the user interface for MAUDE will be helpful, the MDR system is a passive system and has limitations in its use for identifying emerging signals to improve patient safety.

Therefore, FDA claims it is moving to an active surveillance system, leveraging Unique Device Identifiers (UDI) and NEST. Both the MAUDE updates and NEST received funding for development in FY2019 so we look forward to seeing progress in the near future.

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