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JULY 10TH, 2018

# The FAERS Public Dashboard and its Value to the Pharmaceutical Industry

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Resources:

1. FAERS Public Dashboard
2. FAERS Quarterly Data Extract
3. FDA Drug Topics: FDA Adverse Events Reporting System (FAERS) Public Dashboard - January 30, 2018

The FDA has made strides in improving transparency and data access, and has implemented tools to allow the pharmaceutical industry and the public to transform raw data into usable information. It's been eight months since FDA launched one of these tools--the FDA Adverse Event Reporting System (FAERS) Public Dashboard. In this issue, the architects of the FAERS Public Dashboard – Deputy Director of the Regulatory Science Staff Suranjan De, and Acting Team Lead in Regulatory Science Information Sanjay Sahoo—both of CDER's Office of Surveillance and Epidemiology, highlight their work with this new online tool.

***Q: What is the FAERS Public Dashboard?***

**A:** FAERS is a database that contains adverse event reports, medication error reports and product quality complaints resulting in adverse events that were submitted to FDA regarding drugs and therapeutic biologics. These reports are submitted voluntarily by the public via the MedWatch Program, and are required to be submitted by the pharmaceutical industry. The FAERS Public Dashboard is specifically designed for the public to access and view FAERS data in a customizable, searchable format. It allows users to view a summary of adverse event reports received from 1968 to the present or for a specific timeframe.

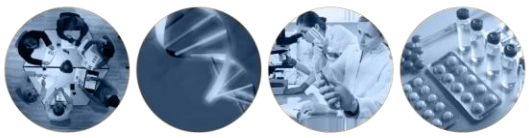
***Q: How is the FAERS Public Dashboard different from the FAERS Quarterly Data Extract Files, OpenFDA and Freedom of Information Act, or FOIA requests?***

**A:** The FAERS Public Dashboard, FAERS Quarterly Data Extract (QDE) Files, and FOIA request data resources are different but complementary in nature.

- The FAERS Public Dashboard is an interactive search tool that allows the user to count and view adverse event reports sent to FDA. In addition to being able to search for adverse drug events, users can "drill down" into an individual case and view approximately 60 data fields specific to the record that include non-confidential information such as demographic, drugs, and therapy information.
- The text-based FAERS QDE Files and OpenFDA provide the same information that is in the FAERS Public Dashboard. These data files are used most often by researchers who prefer to construct their own safety databases rather than using the FAERS Public Dashboard.
- FOIA requests can be made for summary reports by drug and date range. However, these reports include only a subset of the fields that are available in the other public sources mentioned.

***Q: How many reports does the FAERS Public Dashboard contain?***

A: The database consists of more than 15 million reports from 1968 to May 2018. FDA received almost 2 million reports in the past year.



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***Q: Is it possible to download or export data from the FAERS Public Dashboard?***

**A:** Yes. We have made some improvements with the latest updates to the FAERS Public Dashboard, including an option to download and export data.

***Q: Can the user conduct reverse searches, such as searching by adverse event rather than by drug?***

**A:** Yes, this is another new feature. When querying the database, a user can now search for up to five adverse events, and filter down to find a list of drug products that have been associated with the adverse event(s) of interest and view the list of reports. One can also search for up to five drugs and view a list of adverse events.

***Q: Can you describe some limitations of the FAERS Public Dashboard?***

**A:** The FAERS Public Dashboard is an extremely valuable tool, but it does have its limitations, and it is very important to keep these in mind when using it to analyze data:

- The current design does not support searching on more than five product or generic names at the same time.
- The current design does not support a search using both a drug and a specific event.
- The information in these reports reflects only the reporter's observations and opinions and has not been verified or medically confirmed. There is no certainty that a suspected drug caused the reaction, and the reports cannot be used to estimate the incidence or occurrence rates of the reactions reported.
- There are many instances of duplicative and incomplete reports in the system, and some reports do not contain all the necessary information.

***Q: Will there be an analysis of the adverse reports to determine causality?***

**A:** No. The data only includes redacted case level data and an aggregated view of the case data. There is no certainty that the reported event was due to the product. The FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Moreover, the FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether an event will be reported, such as the time a product has been marketed and to what extent an event has been publicized. There are also duplicate reports where the same report was submitted by a consumer and by the sponsor. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population.

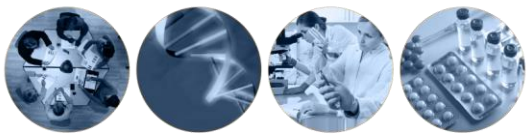
***Q: Are there plans to verify reports or to de-duplicate reports?***

**A:** Case information is received from the reporter, extracted, and displayed on the FAERS Public Dashboard, so no de-duplicate algorithm is applied. On the other hand, nullified cases (e.g., where industry removes their cases by submitting a follow-up report) are not included in FAERS Public Dashboard or in the FAERS QDE. If an active case in the previous quarter was nullified in the current quarter, the case will be present in the previous quarter's extract files, but will not be included in the current quarter's files.

***Q: What type of feedback has FDA received from pharmaceutical industry representatives on how they are using the FAERS Public Dashboard data, or how they anticipate it may help them in the drug development process?***

**A:** Now, anyone can run real-time reports to search for their own data using their own filters and specifications. This is useful to the pharmacovigilance industry and the pharmaceutical industry in general, because it provides them with very recent safety data about the drugs they market. Industry has been able to quickly access the frequency and types of adverse events being reported in the population by using the different filters that the FAERS Public Dashboard offers - by drug name, report type, reporter type, region, reaction, report seriousness or outcome, year, demographics, and more. The data are useful to analyze adverse events for:

- broad patient populations such as the elderly, children, pregnant women, and those with comorbidities
- events with a rare background rate and low frequency
- events that occur shortly after exposure
- detection of events not seen in clinical trials
- identification of reporting trends, possible risk factors, at-risk populations, and other clinically significant emerging safety concerns.



Notably, industry is finding the FAERS Public Dashboard to be valuable in helping them identify gaps in their adverse event reporting, such as reports that may have been submitted to the FDA, but not directly to the sponsor. Sponsors can verify and reconcile the reports they have on file with those in the FAERS Public Dashboard, and confirm that their own reports have been submitted to the FDA.

In addition, they can identify adverse event reports on similar classes of products to compare safety information. Companies are also using these reports to generate safety signals, which can then be analyzed, applied to risk management, and used to guide the development of drug products.

Companies can obtain the "case number" from the FAERS Public Dashboard, which uniquely identifies each adverse event report. Using FOIA, the company can then request a copy of a specific individual case report, which includes a narrative where reporters describe the adverse event in their own words. This "narrative" field is not part of the FAERS Public Dashboard, the FAERS QDE, or FOIA summary reports because it often contains confidential information that FDA must redact before release to the public.

Transparency and safety data analysis tools are essential to helping industry to detect and analyze details of safety signals, and the FAERS Public Dashboard does just that.

***Q: Have you received any industry feedback regarding changes to the database?***

**A:** Yes, we mentioned a few changes earlier that we have implemented in response to industry feedback, and we are considering other changes in the near future as a result of additional comments. We take industry comments seriously and are very receptive to and appreciative of feedback. In the top right corner of the FAERS Public Dashboard, there is a 'Feedback' button via which anyone can submit comments.

You can access the FAERS Public Dashboard by clicking on the 'Drug Safety' drop down bar at www.fda.gov/cdersbia. If you have any questions, view the FAQs section by clicking on the FAQ link in the upper right hand corner of the FAERS Public Dashboard, or reach out to CDER Small Business and Industry Assistance at CDERSBIA@fda.hhs.gov.

Cheers,
Renu Lal, Pharm.D.
CDER Small Business and Industry Assistance

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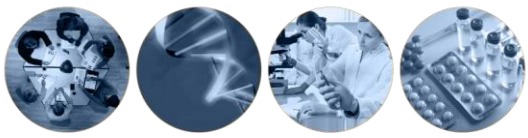

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