

## SAS® Visual Analytics to Inform FDA of Potential Safety Issues for CFSAN-Regulated Products

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### ABSTRACT

Web Intelligence is a business objects web-based application used by the FDA for accessing and querying data files, and ultimately creating reports from multiple databases. The system allows querying of different databases using common business terms, and in the case of the FDA's Center for Food Safety and Applied Nutrition (CFSAN), careful review of dietary supplement information. However, in order to create timely and efficient reports for detection of safety signals leading to adverse events, a more efficient system is needed to obtain and visually display the data. Using SAS® Visual Analytics and SAS® Enterprise Guide® can assist with timely extraction of data from multiple databases commonly used by CFSAN and create a more user friendly interface for management's review to help make key decisions in prevention of adverse events for the public.

### INTRODUCTION

The FDA's Center for Food Safety and Applied Nutrition (CFSAN) is using analytics for early detection signals of adverse events for products including food products and dietary supplements. CFSAN has to work with large amounts and often messy data to detect any signals for potential products. The system allows querying of different databases using common business terms and in the case of the FDA's Center for Food Safety and Nutrition (CFSAN), careful review of dietary supplement information. However, in order to create timely and efficient reports for detection of safety signals leading to adverse events, a more efficient system is needed to obtain and visually display the data. Utilizing SAS tools can assist with timely extraction of data from multiple databases commonly used by CFSAN and create a more user friendly interface for management's review to help make key decisions in prevention of adverse events for the public. SAS has been a great tool for accessing, formatting, and analyzing data in real-time from data sets with large amounts of data that is not efficiently formatted. SAS Enterprise Guide, SAS Studio, and SAS Visual Analytics can automate the process for efficiency and time savings. Through a combination of SAS tools, efficient programming, and SQL querying, solutions can be provided to alert the public about potential threats in a quicker and more insightful way.

### FDA WEB INTELLIGENCE SERVER - ORADSS

Although there are several SAP Business Objects Databases which create reports from SQL data at the FDA, I will focus on ORADSS (Online Reporting, Analysis, and Decision Support System) for purposes of this paper. In general, when creating reports, a query and report generation process occurs as shown in figure 1.

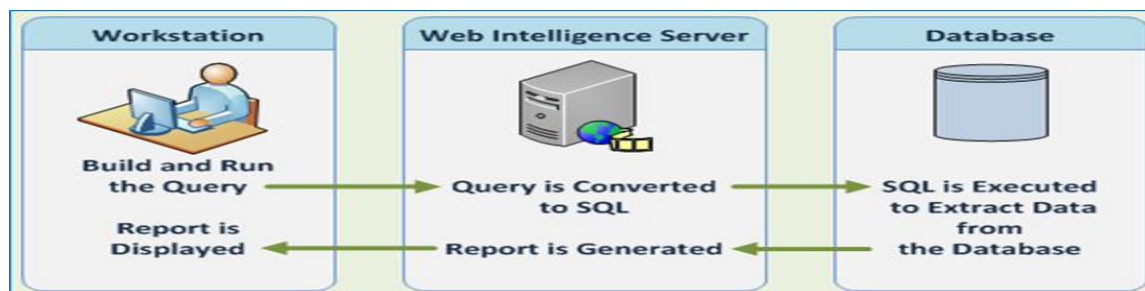
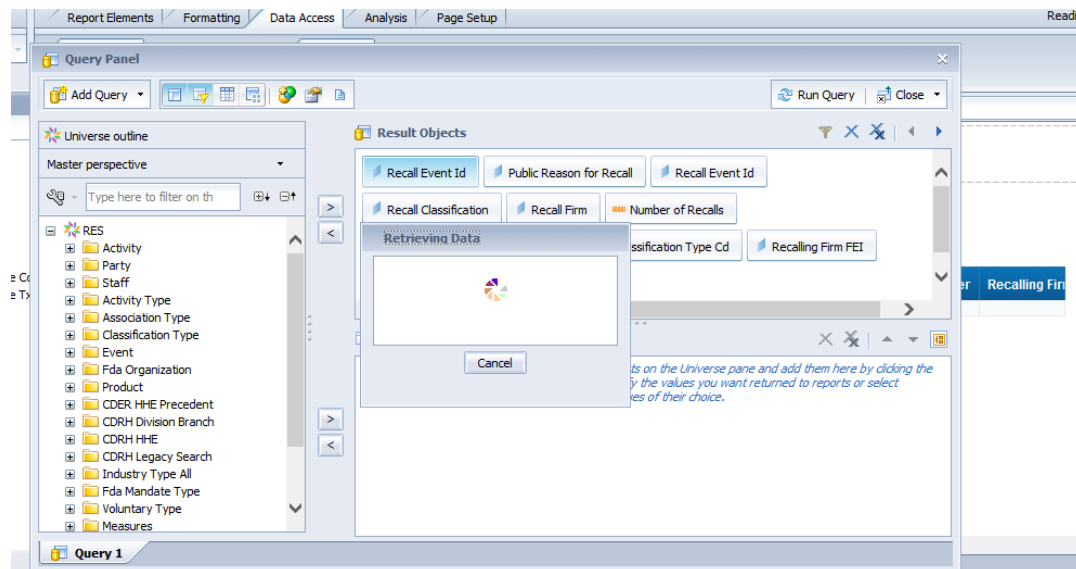


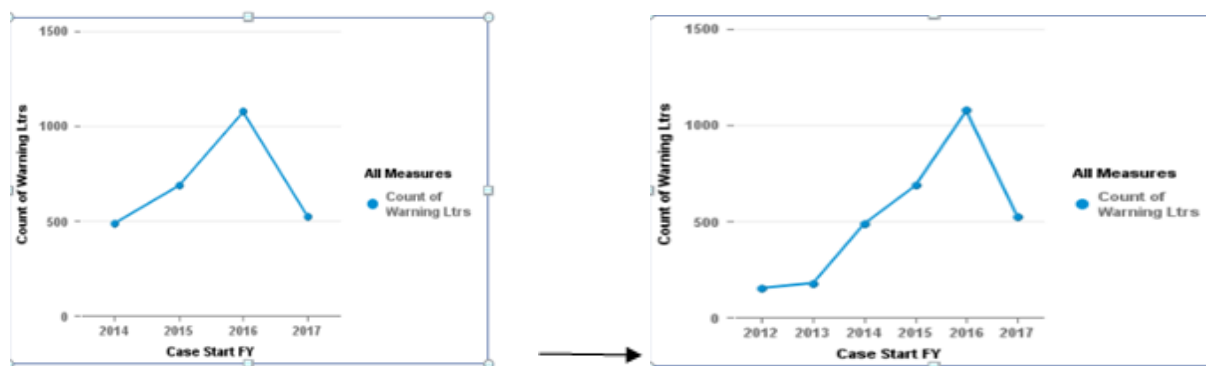
Figure 1. Schematic of the Query & Report Generation Process

As powerful as this approach can be to querying large amounts of data for report generation, issues often arise with processing time and efficiency when querying these databases. Retrieving data can take several minutes to retrieve data as shown in Figure 2.



**Figure 2. ORADSS database retrieving data from a query on the recall universe which can be time consuming.**

In the case of ORADSS, valuable information such as inspection information, recalls, laboratory sample analysis, location, and firm sales provide insight for a dietary supplement that may pose a threat to the public health. Working with this information in ORADSS can generate useful reports, however, the capabilities are time consuming and not interactive. For example, trying to create a line graph to compare warning letters over time requires resubmitting the query to generate the necessary graph in Figure 3.



**Figure 3. ORADSS line graph with data change after changing query. This process requires resubmitting the query.**

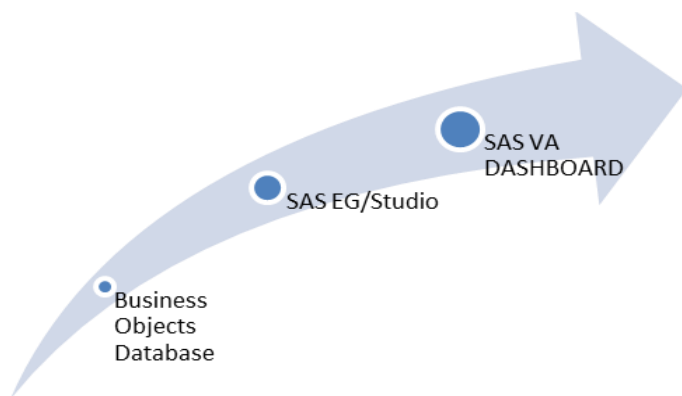
Creating reports using SAS Enterprise Guide/Studio and SAS visual analytics can provide solutions for efficiency and processing time.

## SAS PROGRAMMING AND ANALYTICS TOOLS

When obtaining data from business objects based databases at the FDA, the process to access and querying data can be quite tedious and time consuming. The original data can also be messy due to various formats in data or in data input errors (i.e. 0213 vs 2013). Trying to display visual charts and graphs with up-to-date information requires constant retrieval of information then consecutive preparation

of visuals for interpretation. For example, preparing a PowerPoint presentation requires presenting slides with limited amount of static graphs per slide.

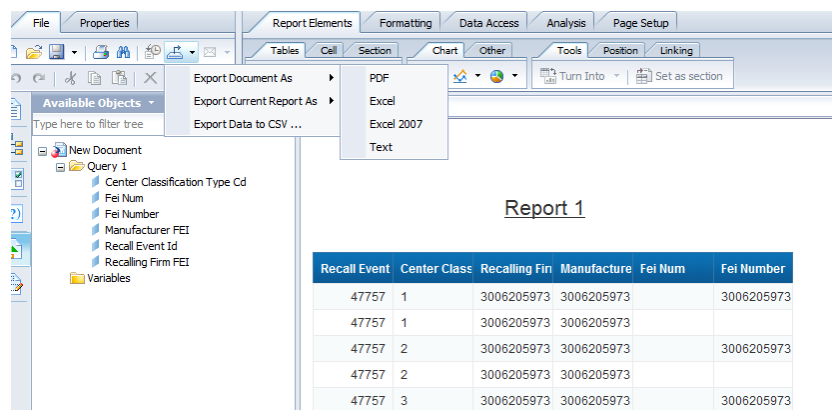
In order to automate the retrieval, format, and presentation of data in a reasonable timeframe, tools such as SAS Visual Analytics, SAS Enterprise Guide, and/or SAS Studio can provide solutions for a previously cumbersome task. The process presented in Figure 4. demonstrates the flow of information from retrieval to presentation.



**Figure 4. Demonstrates the process flow from retrieval to presentation.**

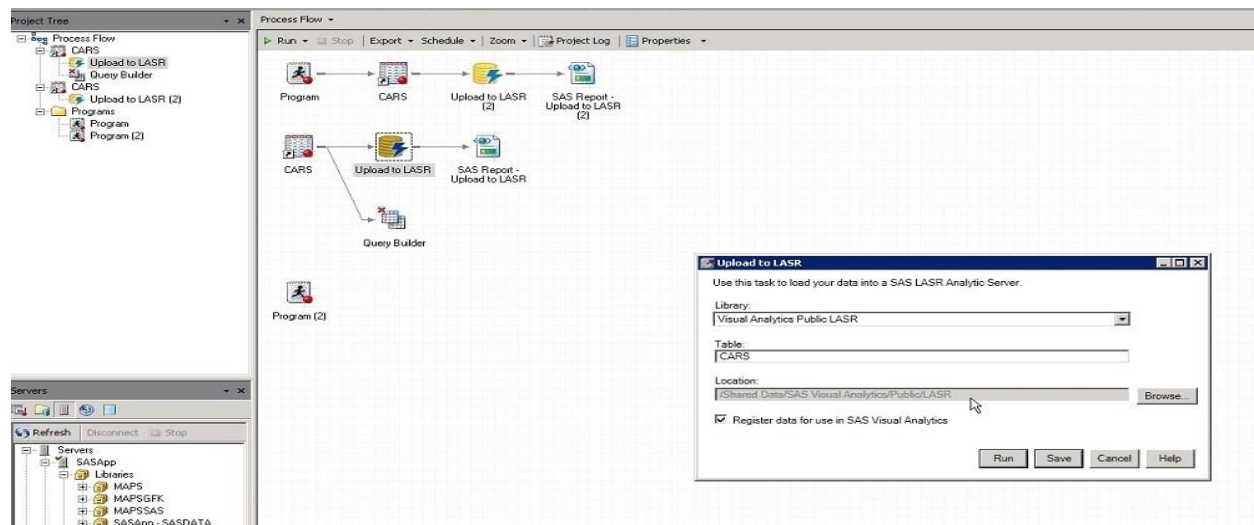
## SAS ENTERPRISE GUIDE & SAS STUDIO

After extracting the data using a SQL query, the report from ORADSS can be converted into different formats including pdf, text, excel, and csv file Figure 5.



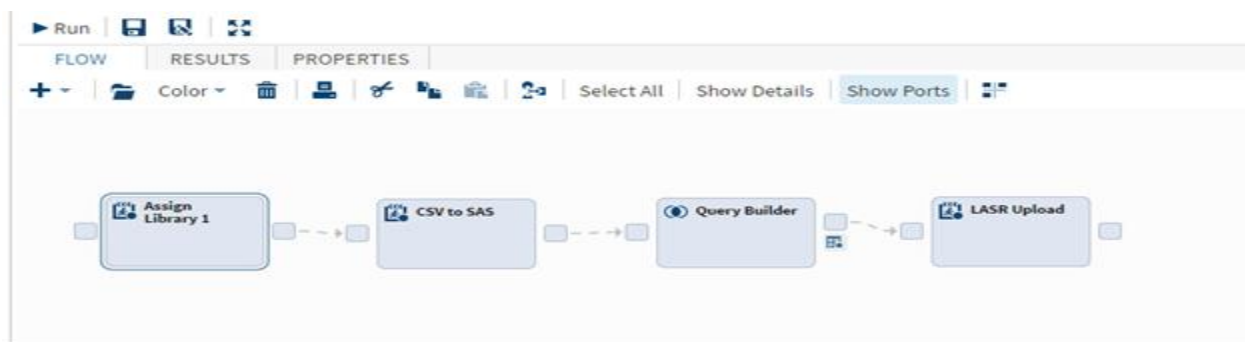
**Figure 5. Demonstrates different file formats that reports can be exported.**

This can be easily uploaded to SAS EG and/or SAS Studio which can be properly formatted as a SAS data set for upload to the SAS LASR Analytic Server. The benefit of using these tools is the ability to automate the process via a process flow especially for data that is updated daily shown in Figure 6.



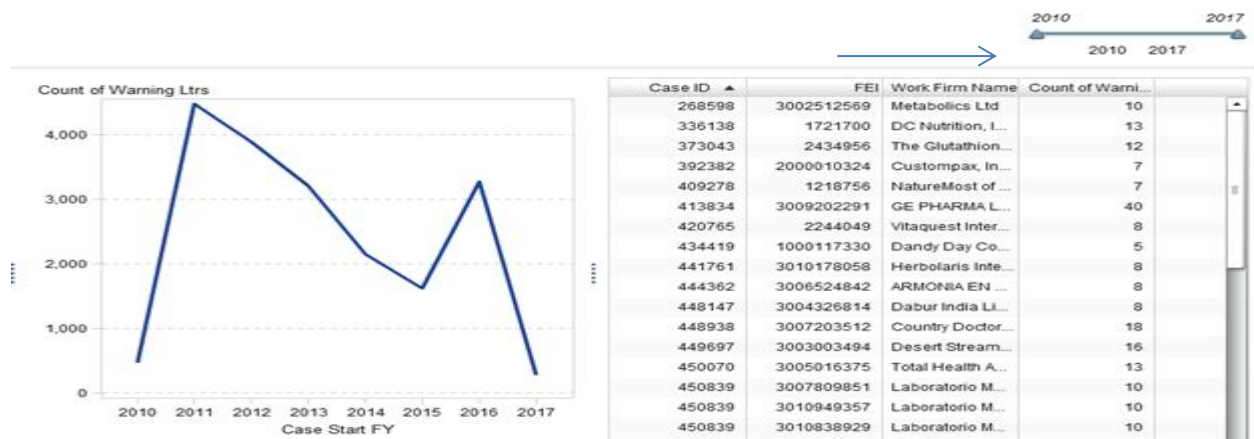
**Figure 6. SAS Enterprise Guide Process Flow**

Alternatively, the process can be accomplished with SAS Studio using additional code to convert the text file to a CSV file and upload to LASR:



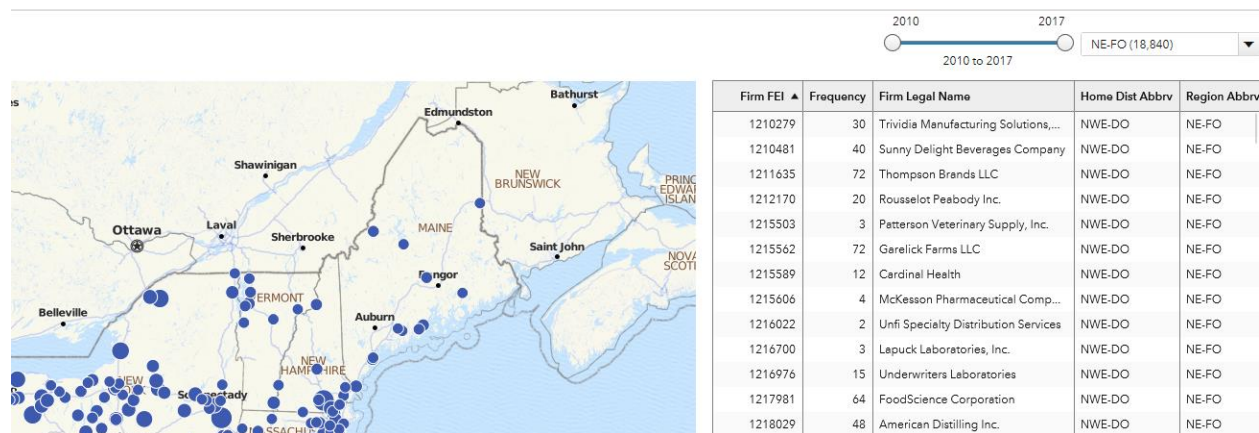
**Figure 7. SAS Studio Process Flow.**

Once the data is uploaded to LASR, it is ready for SAS VA. Creating visually appealing displays and interactive tables really assist the viewer with seeing a potential trend or issue with a particular product and/or firm. Additionally, the display is interactive and doesn't require additional queries such as ORADSS (Figure 3). Variables such as time can be adjusted instantly while corresponding tables/and or graphs adjust with it as well. Figure 8



**Figure 8. SAS Visual Analytics Line Chart.**

Another feature is the mapping capability to pinpoint locations for any particular trends or problem areas. For example, a count of firm inspections can be geographically located with the frequency of those inspections being represented by the size of the highlighted circles in Figure 9.



**Figure 9 SAS Visual Analytics Geo Map**

## CONCLUSION

SAS tools can provide efficient processing of large amounts of data in addition to providing a user friendly interface for data insight into challenging problems. In the case of CFSAN, SAS tools can provide a solution to managing key information extracted from large databases for early detection of warning signals for possible harmful food products and dietary supplements. This can be achieved with tools such as SAS Enterprise Guide, SAS Studio, and SAS Visual Analytics. The goal is to monitor any trends for products that pose a potential health risk and communicate the problem to the public as soon as possible. The future direction is to automatically pull the data directly from ORADSS using tools such as SAS Data Management so the user can bypass ORADSS and query the data and build the report in SAS VA.

## REFERENCES

- ORAU. 2016. *CS154 Domestic Training Manual*. Rockville,MD: FDA.
- SUPPORT / SAMPLES & SAS NOTES. 2015. "Usage Note 56471." Accessed March 6, 2017. <http://support.sas.com/kb/56/471.html>.

## ACKNOWLEDGMENTS

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## CONTACT INFORMATION

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