As part of its Sentinel Initiative, FDA has contracted with Booz Allen Hamilton to identify and characterize potential data sources that may participate in the Sentinel System. The FDA is conducting a survey to better understand the characteristics of data sources. We are asking data owners to complete the attached survey.

Instructions:

Please complete the attached Excel survey and return your responses to Dorothy Stam at Booz Allen Hamilton by <insert date>. Dorothy's email address is stam_dorothy@bah.com. She can also be reached by telephone at 206.652.3018 if you have questions.

Please note there are three tabs to complete in the Excel survey.

Who should complete the survey?

All automated healthcare data owners are encouraged to complete the survey. The FDA is particularly interested in automated healthcare data sources that have the technical capability to link exposure of a FDA-regulated product to a health outcome.

What if an organization has more than one source of data?

If your organization has more than one source of data FDA would like your organization to complete a separate survey for each source of data.

What if an organization has limited resources to respond to the survey?

Although FDA encourages each organization to complete the entire survey, partially completed surveys will also be accepted.

What if an organization has additional supporting information to share with FDA?

In addition to collecting survey responses, FDA is interested in collecting any additional supporting information about a given data source that might help FDA better understand the data source, especially as it relates to its potential participation in the Sentinel System.

Information of interest includes

- Letters of support and curriculum vitae from internal and external researchers that describe their experience working with the data source
- Strengths and potential limitations of the data source for postmarket surveillance
- A description of experience and interest in participating in a distributed data system for postmarket safety surveillance
- Available epidemiologic expertise, data management and programming resources
- Experience (and timeliness) in safety signal detection
- Capacity to validate signals via medical chart review
- Compatibility of existing operations and/or business models with participation in a distributed data system for postmarket safety surveillance
- Description of policies in place for the use of the data within the source for public health purposes
- Processes and agreements that are ordinarily put in place to enable the use of the data for public health purposes, or
- Plans for future data source enhancements

Who should an organization contact if they have questions about the survey?

If questions arise related to the survey, please contact Dorothy Stam at Booz Allen Hamilton. Dorothy's email address is stam_dorothy@bah.com. She can also be reached by telephone at 206.652.3018.

Background

In May 2008, the Secretary of Health and Human Services and the FDA Commissioner announced the Sentinel Initiative. The Sentinel Initiative is a long-term effort by FDA to create a national electronic system for monitoring product safety. Once developed and implemented, the Sentinel System is intended to augment FDA's existing postmarket (primarily passive) safety surveillance systems and to enable FDA to actively gather information about postmarket safety and performance of FDA-regulated products.

As currently envisioned, the Sentinel System will enable FDA to capitalize on the capabilities of multiple, existing automated healthcare data systems (e.g. electronic health record systems, administrative claims databases, registries, others) to strengthen FDA's current safety surveillance capabilities. The Sentinel System will enable queries of disparate data sources quickly and securely for relevant product safety information. Data will continue to be managed by its owners, and only data of organizations who agree to participate in the Sentinel System will be included. Queries would be sent to the appropriate participating data owners, who in turn would, in accordance with existing privacy and security safeguards, evaluate their data and send summary results for Agency review.

For additional background on the Initiative, please see:
http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm.