SUPPORTING STATEMENT FOR ADVERSE EVENT PILOT PROGRAM FOR MEDICAL DEVICES (Medical Product Safety Network (MEDSUN)) 0910-0471

B. Collection of Information Employing Statistical Methods

1. Potential Respondent Universe and Sample Selection Method

The potential respondent universe includes 7,000 hospitals, 17,000 nursing homes, and approximately 20,000 "other" types of health facilities (outpatient treatment centers, outpatient diagnostic centers, emergency health services, and home health services). Since denominator data is unknown for the number and types of incidents that occur with medical devices in the United States, FDA will not use the data collected to make national estimates of devices problems, use problems, etc. In considering the selection of facilities to participate in the pilot, it is important to understand that the main purpose of the eventual, national device surveillance network is not to make precise statistical estimates of frequency of occurrence of adverse medical device events. The purpose of this postmarket surveillance is to obtain signals that public health problems may be emerging and to learn as much as possible about the incidents.

Therefore, it is imperative that facilities be selected that are willing to work closely with FDA to establish a program that generates the types of signals that will enable FDA to take timely action to protect the public health. The greatest participation, and thus the best signals, will be obtained from facilities which have organizational structures and cultures that are willing to share information with the outside world in the interest of increased patient safety. FDA initially recruited those large hospitals that had already expressed interest in joining the program and had national reputations for developing strong patient safety programs. We also recruited some nursing homes in the first year. We are now also in the process of recruiting those larger hospitals (over 100 beds) that fall into our targeting recruiting region that are part of the American Hospital Association database. These new recruits will replace about 50 sites which have not been actively reporting over the past year. These larger hospitals often have adjunct facilities as part of the organization – such as long-term care facilities (similar to nursing homes), outpatient treatment centers, outpatient diagnostic centers, and home health agencies. Larger institutions are also more apt to have experience with diverse medical devices and, given the volume of patients that is admitted each year, are also more likely to have adverse events occur with those medical devices. The types of facilities which will make the most use of the system are in the best position to evaluate the user-friendliness and burden aspects of the system. The usefulness of the database and the search engine for both FDA and the facilities will be best evaluated if we can maximize the number of reports submitted. Therefore, the probability of obtaining input into the system so the system may be tested and refined is greater if larger institutions are enrolled.

Enrollment into the program is voluntary.

2. Information Collection Procedures

The facilities are invited to participate in the pilot project. If they agree to participate, they sign a Memorandum of Participation which describes the reporting procedure they are expected to complete (send adverse event reports via the web – both mandatory and voluntary reports; fill in additional questions; and provide FDA with feedback on the usability of the system).

Each facility receives training in how to participate in the pilot prior to submitting adverse event reports. The facilities report incidents of adverse events via the Internet-based reporting system to FDA via a contractor. The facilities answer the questions that currently appear on the 3500A form as well as some additional questions. The contractor will review the reports for completeness and will follow up with the facility as needed to ensure the report answers the question, "What happened to cause the adverse event?" before the report is made available to FDA.

The contractor will also contact each facility as needed to ascertain why any of the additional voluntary questions were left unanswered, and to obtain necessary follow up details.

3. Methods to Maximize Response Rates

Every effort is made to maximize responses. However, in postmarket surveillance that is based on numerator, rather than denominator, data, obtaining important signals that problems may be occurring is more critical than obtaining large numbers of reports.

Therefore, over the 5 years of data collection, we have developed educational materials that the hospitals may use to teach staff to recognize problems with the use of medical devices, both 'potential for harm' scenarios as well as those adverse events where a device may have place a role, and to report those problems within the hospitals – so they may then be sent into the MedSun program. We provide audio conferences for hospital staff to raise awareness about the importance of reporting, and in addition, we are targeting specific areas of the hospitals to obtain information about device problems in high-risk areas and in vulnerable populations, i.e. pediatric ICUs, neonatal ICUs, Electrophysiology Laboratories, and hospital laboratories. We also are piloting the use of regional representatives who visit the MedSun sites to help in educating staff and to help promote recognition of events and reporting of those events.

In addition, if a facility has sent less than 2 reports in the first 6-months of entering the pilot, the contractor calls the facility contact person to ask how the system seems to be working, if the facility needs more training in the mechanics of working in the pilot project, etc. This gentle probing is to remind the facility contact person that the success of the project depends on each facility forwarding medical device related adverse events

so FDA, the device manufacturers, and the clinical community may learn about, understand, and solve problems with the use of medical devices.

4. Test of Procedures

The need for user facilities to report adverse events associated with medical devices is currently mandated by law, so the fundamental mechanics of how to work with a reporting program is well-known to facilities. Before MedSun, all reporting had been a paper system, so this pilot was the first test of a new electronic version.

We have been collecting data in MedSun for 5 years and our MedSun sites tell us they much prefer the on-line system to the paper system.

5. Statistical Consultation and Independent Review

Social and Scientific Systems (this company purchased CODA, the contractor cited in the past Justifications) the contractor tasked with developing and implementing the MedSun program, assists FDA in determining the design of the data collection.

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