

Sentrx Helps Consumer Health Care Company Successfully Implement Risk Management Program

The Business Issue

The Consumer Health Care division of a major pharmaceutical company planned to market two dosage forms of a new product recently approved in the United States. Since these dosages were higher than those of similar treatments, the U.S. Food and Drug Administration (FDA) required the company to monitor real-world experience in order to identify safety signals across the population using the product. The company agreed to report the results of the risk management program to the FDA within six months of launch.

The Sentrx Solution

Needing a partner with the expertise and infrastructure to design and implement an Outreach Risk Surveillance™ program, the pharmaceutical company turned to Sentrx. The Sentrx project team worked closely with the sponsor's marketing, safety, epidemiology, outcomes and information technology professionals to develop the protocol and survey, design the campaign, configure the telephony and computer systems, and hire and train qualified professional staff.

Study Parameters

Program participation was initiated with packaging information soliciting registrants for the study. A small card advertising the program contained a toll-free number and Web address, either of which could be used to register, and was inserted into several hundred thousand boxes of each dosage form prior to distribution. A motivational payment was offered once at registration and again upon survey completion.

The project team assumed that 50% of those who registered for the survey would actually be reached. The goal was to complete up to 5,000 medical interviews in each dosage group, for a total of up to 10,000 completed surveys in a time frame of approximately 4 months. Sentrx provided the inbound call center using their business partner Affina, a pioneer in the customer service industry, to enroll this volume of participants. Sentrx also configured the registration Website and assumed that 10% of the participants would enroll through the Internet.

In order to participate in the study, registrants were required to be at least 18 years of age, consent to the use of medical information gathered for research purposes, and have taken at least one dose of the product upon registration. The protocol then specified that the participant be interviewed within 2 to 3 weeks following initiation of therapy. In order to meet this stringent requirement, Sentrx utilized OnTrak™ Scheduler, the enrollment and scheduling module of the Sentrx SafetyTrak[®] Portal. OnTrak™ Scheduler captured the precise date and time for the medical interview to take place, based on the needs of the participant and the requirements of the study.

The project team estimated that 50% of the population interviewed would respond positively to questions regarding expected non-serious adverse events. Spontaneously reported adverse events also needed to be captured. Thus, it was important for the survey to be conducted by safety-trained health care professionals.

Implementation

Sentrx Safety Monitors, experienced in supporting patients and consumers, administered the medical interviews. These health care professionals made outbound calls Monday through Friday, 9 a.m. to 9 p.m., and on Saturdays and Sundays, 9 a.m. to 5 p.m., from the Sentrx Safety Response Center in Little Falls, New Jersey. Interviews were conducted in all 50 states and in U.S. territories including Puerto Rico, American Samoa and the Marshall Islands. Since the outbound calls were prescheduled with OnTrak™ Scheduler, Sentrx was able to maximize the use of this highly skilled labor pool.

The survey requested information such as age, medical history, concomitant medications, outcome of treatment, social behavior, and adverse events. De-identified information captured during the survey was made available to the pharmaceutical company in predetermined summary tables.

When a serious adverse event was reported during the medical interview, the Sentrx Safety Monitor investigated the case and prepared the expedited report. A Sentrx Medical Safety Officer was always available to provide consultation and perform medical review of every serious adverse event.

The Results

The Sentrx solution exceeded the expectations of the pharmaceutical company. Although a smaller number of consumers registered than expected, the required amount of surveys was completed on time. This was because the professional and persistent Sentrx team, equipped with OnTrak™ Scheduler, accomplished a survey completion rate of greater than 75%. Once engaged with a consumer on the phone, Sentrx Safety Monitors were able to finish the 38-question medical interview more than 95% of the time.

Both the pharmaceutical company and Sentrx were delighted that more than 30% of participants enrolled in the study through the Website. This helped to reduce costs and increase the efficiency of the registration process.

The pharmaceutical company found that the number and severity of non-serious adverse events were no greater than expected and that the number of serious adverse events was far less than anticipated, even at the higher dosage. Responses from the participants also indicated the product was being used as directed.

The Benefits

The Sentrx Outreach Risk Surveillance Program helped the Consumer Health Care division to:

- Increase brand image with efficient yet caring consumer contact
- Meet FDA regulations on time and within budget
- Ensure the safe and effective use of an important new product

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