

Sentrx Helps Pharmaceutical Company Meet Post-Marketing Commitments

The Challenge

A specialty pharmaceutical company with its first new drug in review had much to accomplish. The therapy was novel in its effectiveness, but a very small percentage of patients in clinical trials experienced an allergic reaction that required immediate attention. Approval from the U.S. Food and Drug Administration (FDA) was contingent upon the development of a method to ensure only qualified physicians administered the drug.

The Solution

The company turned to Sentrx for its unique combination of drug safety expertise and technology-enabled solutions. Sentrx designed and implemented a performance-linked access system to control distribution of the therapy, as well as a post-marketing commitment study to measure the effectiveness of the risk management program.

Performance-Linked Access System

Sentrx configured and validated a performance-linked access system using OnTrak™ Controller, a module of the ultra-secure SafetyTrak[®] Technology Suite, in less than sixty days. This enabled the company to meet an aggressive timetable for product launch.

Important objectives of the risk management program included the education of prescribing physicians and certification of their qualification to administer the drug appropriately. Physicians registered on the Web and by telephone to the Sentrx Safety Response Center. A signed attestation was digitally faxed or scanned and attached to the electronic record in the physician registry, activating them as a prescriber.

When a hospital pharmacy was associated with the prescriber, the pharmacist-in-charge also attested to an understanding of the drug's risks and benefits and agreed to confirm prescriber activation before dispensing the product.

As an additional level of control, distributors were registered in OnTrak™ Controller. They accessed the system to confirm that physicians and associated hospital pharmacies were activated in the program before fulfilling an order for the drug.

Post-Marketing Commitment Study

The FDA required the company to conduct rolling studies on random samples of all activated prescribers to survey their knowledge of the product and their responsibilities under the risk management program. To perform these surveys efficiently and effectively, Sentrx configured a physician questionnaire in SurveyTrak™ Interviewer, another module of the SafetyTrak[®] Technology Suite. OnTrak™ Controller generated unique identification codes for physician

login and managed the remuneration upon completion. SurveyTrak Interviewer presented the questions and stored the responses for export into data analysis software. Information about the survey, such as identification number, completion status and completion date, was transferred to OnTrak Controller.

At regular intervals, twenty percent of physicians in the registry were randomly selected to receive the questionnaire. The group was faxed an announcement of the upcoming survey using automated scripting in the Sentrx RightFax server. After activating the questionnaire in the ultra-secure Sentrx web environment, a survey request was faxed to the group with instructions for access. Thirty days later, a second request was faxed to those physicians that did not complete the survey.

By conducting the survey electronically, the company achieved a completion rate of nearly 20%, a 10-fold improvement over typical response rates achieved with paper surveys sent through the postal system. The physician registry was leveraged to implement the post-marketing commitment study on time and under budget.

The Benefits

Utilizing the SafetyTrak® Technology Suite, Sentrx helped the specialty pharmaceutical company:

- Gain FDA approval and launch the new therapy within sixty days
- Meet post-marketing commitments
- Maximize benefits and minimize risks to patients



Overlook at Great Notch
150 Clove Road
Little Falls, NJ 07424