



## SafetyTrak<sup>®</sup> Risk Management Solution

### *How do you move your drug from “Approvable” to “Approved”—*

The New Drug Application has been under review by regulatory authorities for the past 18 months. The agency recognizes the potential of the innovative therapy to treat millions of people effectively, but the Integrated Safety Summary suggests a segment of the population may be at an elevated risk for serious adverse effects. The drug is “approvable,” they say, but it cannot be marketed without a method to protect these high-risk patients. Is it possible to design and build a program that’s effective enough to satisfy the regulatory agency, yet simple enough that physicians and patients will participate? Can it be implemented quickly enough to coincide with a successful launch?

### *And keep it there?*

The list of prescription products removed from the market is growing exponentially. Drug regimens are becoming more complex, and the aging population takes more concomitant medications and has more underlying medical problems than ever before. Because clinical trials study a relatively small and controlled patient population over a relatively short period of time, they cannot be relied upon to identify all the safety issues that may surface after approval. How can a company maintain the long-term viability of a product franchise when new black box warnings and traditional communication methods to health care professionals have little effect on prescribing habits?

### *The answer is Sentrx*

Sentrx is a leading provider of technology-enabled services and solutions for global drug safety. Our mission as a corporation is to manage the safety risks associated with developing and marketing pharmaceuticals. The Sentrx SafetyTrak<sup>®</sup> Risk Management Solution is a powerful combination of people, process and technology. Our multilingual Safety Response Center is staffed with health care professionals who interact with patients, physicians and pharmacists to obtain the data needed to assess and confront risk. Highly skilled staff and well-defined pharmacovigilance processes ensure that adverse events and other events of interest are readily identified and thoroughly investigated. And our Web-based SafetyTrak<sup>®</sup> Technology Suite provides the infrastructure to proactively monitor the use of products in the general population, allowing the benefit/risk ratio to be assessed or improved.

### *Technology-Enabled Solutions to Safety Risk Management*

Sentrx is capturing the power of the Internet to successfully manage risk. We have partnered with specialists in recruitment and leading providers of online medical information with strong relationships to physicians, pharmacists and consumers. As a result, Sentrx provides effective and efficient education, recruitment and enrollment into all phases and types of risk management programs.

Sentrx also offers a unique set of tools for risk intervention. The modules of our SafetyTrak<sup>®</sup> Technology Suite provide the building blocks of Education & Outreach, Guidance & Surveillance and Restricted Access programs:

<b>OnTrak™ Controller</b>	Used to register participants, schedule and track interactions, and control prescribing
<b>SurveyTrak™ Interviewer</b>	Provides the framework to create and administer medical interviews, surveys and questionnaires
<b>EventTrak™ Reporter</b>	Allows browser-based case intake and active query management of adverse events and product complaints



### **Education & Outreach Programs**

For some new products, the package insert will not be enough to ensure their safe use. Regulatory authorities such as the U.S. Food and Drug Administration are beginning to request additional methods be employed to educate health professionals and patients about potential risks.

Working with our partners, Sentrx can reach hundreds of thousands of physicians by therapeutic area with electronic mail and outbound fax to target your message to those who will be prescribing your product. Our services include the Web's most robust integrated medical information and educational tools, including market-leading Continuing Medical Education. We can also reach patients and consumers directly with online content.

### **Guidance & Surveillance Programs**

For other products, Education & Outreach is only the first phase in managing risk. It may be imperative to know if your new product is being taken as prescribed; or if physicians are heeding the warnings in the latest Dear Health Care Professional letter; or what the numerator and denominator are for certain adverse events or events of interest reported.

Sentrx provides the infrastructure to proactively gather information on how your product is being used and tolerated in patients in a real-world setting. After recruitment, OnTrak™ Controller allows physicians, patients and/or pharmacists to register for your program on the Web or by telephone. From there, Guidance & Surveillance may include:

- Interviews with physicians and pharmacists to confirm the receipt and understanding of a Dear Health Care Professional letter
- Interviews with patients to determine their understanding of proper use and to solicit adverse events proactively
- Certification programs to train practitioners on contraindicated conditions and monitoring for adverse events

If medical interviews or surveys are part of your risk management protocol, OnTrak™ Controller allows participants to select the most convenient date and time to be contacted by our Safety Monitors. This accommodation increases the rate of successful survey completion and allows sponsors to collect data within a certain therapy window. SurveyTrak™ Interviewer, with its browser-based interface, drop-down menus and nested questions, ensures that consistent and accurate information is collected. Ultra-secure Web access to authorized entities allows results to be monitored in real time.

## Restricted Access Programs

A few products need stringent interventions to maintain a favorable benefit/risk ratio. Sentrx Restricted Access programs ensure not only that participants are made aware of any contraindicated risk factors, but also that the benefit/risk assessment is formally reviewed and documented for each patient before a drug is dispensed. Patients, physicians, pharmacists and/or distributors register to use, prescribe, dispense or ship your product using OnTrak™ Controller. Information such as patient history, concomitant medications or lab test results is collected to determine the eligibility of patients to receive the drug. Your Restricted Access program can then be configured to provide verifiable links, such as:

- Informed consent, obtained via phone, digital fax, Web or e-mail, and stored in the online registry to document that physicians and patients are aware of potential adverse events and the importance of monitoring and reporting
- Creation of a unique patient identification number and prescription number in the online registry, which the pharmacist compares to verify eligibility before dispensing the drug
- Creation of a unique physician or hospital pharmacy identification number in the online registry, checked by authorized distributors of your product to ensure those entities are certified to receive shipment of the drug

## SafetyTrak® Risk Management Solution

<b>Features</b>	<b>Benefits</b>
• Provides outbound as well as inbound call capability by experienced health care professionals	• Proactively engages patients, physicians, and pharmacists in risk management
• Accessible via the World Wide Web or by telephone to the Sentrx Safety Response Center, 24 hours a day, 7 days a week	• Simplifies enrollment and reporting • Eliminates paper forms • Maximizes participation
• OnTrack™ Controller manages registration and interview schedules	• Effectively screens candidates • Increases survey completion rate • Maximizes use of skilled labor
• Prescription control module assigns physician and patient ID numbers and prescription confirmation numbers	• Provides verifiable link between prescription qualification and dispensing activity
• SurveyTrak™ Interviewer guides the Sentrx Safety Monitor or participant through the medical interview	• Ensures accuracy and consistency of data collected • Improves risk evaluation
• Accepts consent forms, test results and any other faxed documentation as digital input and attaches it electronically to the patient record	• Eliminates delays associated with mailing and processing paper • Increases the effectiveness of a risk management program
• Easily tailored to different languages and regulatory environments	• Provides a global solution
• Imports pre-existing physician and patient information from other databases	• Accelerates initiation of program
• Provides access to collected information in real time	• Ensures program compliance without on-site audits • Speeds the identification of benefits and risks
• Provides personalized views of the collected data for authorized interests groups, such as safety departments, clinical trial data managers or regulatory agencies	• Maximizes program benefits to all stakeholders without sacrificing confidentiality
• 21 CFR Part 11 and HIPAA compliant	• Provides benefits of electronic signature • Ensures confidentiality of medical records

## ***Modular Design and Implementation***

The modular design of the SafetyTrak® Risk Management Solution provides the building blocks to rapidly deploy Education & Outreach, Guidance & Surveillance or Restricted Access programs. Its flexibility allows pilot programs to be built, tested and modified before full-scale implementation to demonstrate that the risk management intervention will meet its stated objectives. It can also be employed in a baseline study to assess the level of risk a new product should be assigned or to evaluate the effectiveness of a current risk intervention.

## ***Security is the Design Criteria***

A risk management program should never put a patient's confidential medical records at risk. That's why Sentrx has applied the highest level of security, privacy and control to the SafetyTrak® Technology Suite. To ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the varied European country patient privacy standards, we have partnered with The ESP Group, LLC, a cyber-security company that leverages the benefits of the Internet without compromising security.

Most security solutions address only one of the many vulnerabilities an application faces when it is delivered over the Internet, providing the equivalent of a strong lock on the front door while the back and side doors are wide open. But ESP provides the full circle of security practices necessary to protect sensitive information. The Web-based application management and delivery service that The ESP Group provides was originally developed for secure collaboration by the US national security and intelligence community, and it is now used by many US and European military and intelligence agencies. Sentrx has the exclusive rights to develop and market applications using ESP technology to the pharmaceutical industry, so no other company can offer the proven security of the SafetyTrak® Technology Suite.

## ***At Sentrx, Safety Matters***

To learn how Sentrx can help move your drug from "approvable" to "approved," call us at 1-888-399-8032, ext 261; or visit our Web site at [www.sentrx.com](http://www.sentrx.com).



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

1-888-399-8032

[www.sentrx.com](http://www.sentrx.com)

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