

Safeguarding Success

Unprecedented Coordination Eases New Drug Entry

Challenge

An emerging company with a novel drug treatment faced significant challenges meeting clinical and post-marketing safety requirements.

Solution

Quintiles designed and implemented a custom safety program to meet their needs, using an integrated lifecycle approach that coordinates safety across different phases and functions.

Results

Providing a comprehensive safety program with an integrated approach, we were able to help the customer navigate complex safety requirements while improving efficiency, compliance and accuracy.

As a proven ally that delivers integrated safety services, Quintiles served as the customer's *de facto* in-house pharmacovigilance department.

Rapidly Build a Comprehensive Safety Program

When new companies emerge into the pharma market, the institutional competencies they need to succeed, including safety monitoring, may not be as fully developed as the innovative capabilities that brought them onto the stage.

In a global trial of a novel drug for the treatment of a low-incidence condition, our customer faced significant challenges with clinical and post-marketing safety. This emerging company — which had a rich pipeline with one product close to approval — did not have previous drug safety experience and sufficient standard operating procedures or processes in place to address safety requirements. They had an immediate need for a CRO with the expertise and flexibility to provide a full range of safety and risk management solutions.

Custom Integrated Approach

With proven expertise and resources on a global scale, Quintiles was able to help. The customer asked Quintiles to provide safety monitoring and reporting for Phase III trials across the U.S., Europe, South Africa and South America. We designed and implemented a custom safety program to meet their needs, using an integrated lifecycle approach that coordinates safety across different phases and functions. In contrast to a traditional segmented approach, we incorporated safety publishing, case processing and medical information into a coordinated, cohesive plan. Our team also performed services from peri-approval tasks of risk management planning, pharmacovigilance description and registration to post-marketing database set-up and medical information and processes.

Providing a comprehensive safety program with an integrated approach, we were able to help the customer navigate complex safety requirements while improving efficiency, compliance and accuracy.

With a view that took in the entire development lifecycle, we merged safety information from earlier phases that had predated our involvement into a single database. One of our safety experts was assigned as the dedicated medical lead for the duration of the project, bringing continuity and efficiency to the work and clarity to the product's submission for market approval.

Implementing an Integrated Safety Plan

We customized a comprehensive safety program for the customer's unique needs, integrating the following services:

Safety Publishing

- > *EU risk management plan*
- > *Standard operating procedures (SOPs)*
- > *Aggregate reports (PSURs)*

Case Processing

- > *Safety database set-up and maintenance*
- > *EudraVigilance registration*
- > *Clinical and post-marketing safety case processing*
- > *In-line safety surveillance*
- > *Expedited and periodic regulatory reporting*

Medical Information

- > *Multilingual call center support*
- > *Literature searches*
- > *Spontaneous adverse drug reaction collection*

In essence, the customer looked to Quintiles as a mentor to guide them each step of the way. Serving as a virtual pharmacovigilance department, we had the expertise and product knowledge to anticipate challenges and provide possible solutions as they arose. For example, Quintiles helped the customer explore named patient and compassionate use programs as a possible alternative for entering into markets prior to approval.

As the customer's needs expanded, we grew our relationship to support their medical information program for post-marketing in Europe. With additional call centers in the U.S. and Singapore, we're ready to support the customer as the product enters new markets.

Comprehensive Safety Accelerates Market Entry

Providing a comprehensive safety program with an integrated approach, we were able to help the customer navigate complex safety requirements while improving efficiency, compliance and accuracy.

As a proven ally that delivers integrated safety services, we served as the customer's *de facto* in-house pharmacovigilance department and they entrusted us with increasing responsibilities. When the customer sought approval in two European countries, Quintiles helped to successfully prepare one of the first Risk Management Plans ever submitted to the EMEA, (now known as EMA), speeding market approval. Even with no industry precedent to follow, our intimate knowledge of the product helped us prepare the successful EU-RMP, which was accepted without alterations or delays.

Working toward imminent approval in the U.S. and South America, our customer is better prepared to enter those markets faster — with insights and the support of Quintiles for a successful expansion into the global market.

Contact Us:

In the US: 1 877 988 2100

In Europe: +44 (0) 1344 708000

In other areas: +1 919 998 2000

On the web: www.quintiles.com/safety

Email: safety@quintiles.com

