Customer Story

Medytox

Challenge

Navigate a complicated regulatory landscape to enter the global marketplace.

Clinical trial analytics help a biopharma leader go global

A Korean biopharmaceutical trailblazer prepares to enter the global market by 'strengthening internal infrastructure and improving clinical quality'

Korean biopharmaceutical company Medytox is best known for pioneering Neuronox, a botulinum toxin type A (BTX-A)-based product indicated for both aesthetic and medical uses as a treatment for muscle spasticity. Since Medytox's success in the Korean market with Neuronox, the company has retained a competitive position with the launch of hyaluronic acid dermal filler Neuramis and Innotox, the world's first liquid BTX-A formulation, in both Korea and Japan.

Ongoing R&D has also proved fruitful: Medytox recently obtained regulatory approval for Coretox®, an advanced new BTX-A product that excludes animal derivatives and non-toxin proteins from its ingredients and is therefore safer than its predecessors. Not only will continued R&D help to elucidate better, safer formulations like Coretox, researchers also hope to uncover new therapeutic applications for the protein.

Joo Hwan Lee, Head of Clinical Development, manages Medytox's development team and is responsible for designing clinical development plans and trials, running clinical trial operations and overseeing compliance and the reporting process. In order to optimize all these and other activities – and thereby pave the way for Medytox's future successes – Lee keeps a watchful eye on the market. In Korea, he says, the regulatory landscape is now more volatile than ever before.

Tightening national regulations present exigent hurdles for R&D efforts

"The Korean pharmaceutical industry is facing many new challenges related to price cuts, the development of new synthetic drugs, intensifying competition in the domestic market, frequent changes in policy and tightened regulations," Lee says. Although increased interest in biotechnology has to some extent boosted biosimilar production, facility investment and long development periods have been noticeable barriers to success on the Korean market even in this arena. "Clinical development costs have risen with strengthened regulations. And in response to limitations in the domestic market, Medytox is stepping up its efforts to tackle the global market."

Expanding the company's reach beyond its borders, however, means staying abreast of foreign regulatory standards – and ensuring Medytox operations are compliant even as those regulations evolve. "As development costs and clinical competition increase, the demand for faster clinical trials – that also meet regulatory compliance – have intensified. New guidelines related to risk-based monitoring enacted by the FDA, EMA and other regulatory agencies have also had significant influence."

So it goes without saying that preparation is a must for Lee's division. "In order to enter the overseas markets," Lee says, "we first need to strengthen our internal infrastructure and improve clinical quality in accordance with the regulations of each country." That effort requires advanced market analysis and monitoring. Lee says Medytox aims to "minimize risk through data monitoring and the standardization of clinical data."

Consolidated data discovery, analysis and reporting, purpose-built for clinical trials

The complex, multilevel data generated in clinical trials is a veritable minefield of data hurdles for organizations like Medytox. To be

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>
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competitive at home and abroad, Medytox has the added challenge of performing accurate analytics under serious time constraints. That's why Lee introduced JMP® Clinical, a specialty software package from SAS that will enable Medytox scientists to both improve clinical quality and reduce processing time.

"JMP Clinical is a product that stands out in its focus on clinical trials," Lee says. "Once data is standardized from the data collection stage, JMP Clinical helps with analysis and interpretation." In bringing together the data exploration features of JMP and the rich analytics of SAS® in one product, JMP Clinical is purpose-built to provide specialized analytics and a streamlined user interface for the clinical setting. With simplified features linking management and reporting – and superior options for flexible sharing – JMP Clinical is an indispensable tool for the Medytox R&D team as they observe and explore trends and report results.

Medytox scientists now rely on JMP Clinical for risk-based monitoring, data distribution review, safety reporting and data exploration. Lee says visualizations – the core feature of JMP data exploration – help users synthesize and understand data in just a few clicks. Data visualization enables scientists to easily identify and combine adverse events, combined drugs, past medical histories and other basic clinical trial information. Lee says one of the greatest advantages of JMP Clinical is its powerful data cleaning mechanisms that allow users to identify outliers or problematic data in very little time.

Next-level clinical trial monitoring and safety reporting

With risk-based monitoring functionality in JMP Clinical, Medytox is able to limit clinical trial costs by eliminating the need for on-site reviews. Moreover, the tool promises to help Medytox's development team streamline monitoring processes that might otherwise threaten to delay time-sensitive releases. Lee says implementing efficient, effective internal data monitoring processes is central to ensuring that clinical trials are run expeditiously. "JMP Clinical allows you to easily transform the format of the data you need to submit to the regulatory body," he says. "If you have a standardized data set, you can easily get multiple useful clinical trial reports without any special manipulation."

Lee says it's "easy to generate reviews by simply linking the data set – something that, with other analysis tools, can only be obtained through a series of operations. The Safety Report feature in JMP Clinical is a good example of an innovative feature – it can handle more data than you might think, so it can be very useful for clinical investigators. In addition, JMP Clinical safety reports show the risk by country and institution using the risk assessment model of clinical trials. This provides great convenience to those who run clinical trials."

Moreover, JMP Clinical enables a sharing architecture that provides an additional range of file sharing and cloud-driven capabilities to users. "The transition from paper-based clinical trials to cloud-based clinical trials has made it possible to monitor data in real time. And JMP Clinical serves as a useful tool in this regard," Lee notes.

As Medytox launches into the next phase of its life as an international biopharmaceutical player, the organization is looking to Lee to minimize the risk of noncompliance with regulatory policy or inefficiencies in the company's clinical monitoring and reporting methods. But he doesn't have to go it alone; luckily JMP Clinical is uniquely poised to help Medytox navigate the rough waters of a volatile regulatory landscape.

Solution

Consolidate and improve processes for data exploration and cleaning, risk-based monitoring and reporting with JMP Clinical.

Results

JMP Clinical has helped Medytox better position itself to enter the global market as a leader and pioneer of ongoing BTX-A therapies.

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