

Enabling Transformation

Rapid Trial Transfer Helps European Specialty Pharma Realize Bold Ambitions

In 2008, Sweden's Biovitrum found an ideal opportunity to realize its ambitions of transforming itself into a fully integrated specialty pharmaceutical company from a biotech discovery and early clinical development company. Biovitrum acquired global rights for two marketed products and an exclusive global license for an additional product that were well aligned with the company's specialist strategy and existing therapeutic interests.

But there was one big catch: To seize the opportunity and close the deal in December 2008, Biovitrum had only three months from agreement signature in September 2008 to have all services in place to support the Marketing Authorizations worldwide. This also included contract services to transfer in global post-marketing commitment trials associated with one of the products. A contract research organization with experience managing complex, demanding programs would have to be brought on board – fast. The dynamics of the transfer would require that CRO to be especially proficient in a host of complementary disciplines, especially with regards to clinical, safety and regulatory expertise.



Bringing It All Together

Successful past collaboration between Biovitrum and Quintiles on Phase I and Phase II studies in Sweden set the stage for another potential collaboration. After a comprehensive three-day consulting session with Quintiles' project management, regulatory and pharmacovigilance team leads, Biovitrum determined that Quintiles was qualified to guide a successful transfer under especially challenging conditions.

To accelerate the entire process, a group of experts from Quintiles quickly became part of the Biovitrum delivery engine. Through a managed partnership approach, everything was deftly and meticulously planned from the outset – how study data and clinical dossiers would

be transferred, how an IND in front of the FDA would be transitioned, how MAH filings and product registrations from more than 30 countries would be managed, how the clinical trial program would be transferred, etc. To successfully execute its plan, Quintiles assembled a global team of its own experts representing a broad range of functions, including those with rich project management, regulatory, pharmacovigilance, laboratory, clinical development and commercialization experience.

In short, Biovitrum's team capitalized on Quintiles' complementary brainpower – and hands and feet, for that matter – to create an ideal infrastructure to support the new products.

Fulfilling the Promise

In December 2008, Biovitrum completed the deal. It marked a critical milestone in Biovitrum's evolution, helping validate the company as a true development force fueled by a new, viable, robust revenue stream. It also helped the company establish a broader geographic presence and strengthen its position as a specialty pharmaceutical company.

At a time when emerging biotechnology companies around the globe were finding a difficult, unforgiving operating climate, Biovitrum found the right ally – one that could provide precisely the right expertise when the right opportunity appeared.

Contact Us:

In the US: 1 877 988 2100

In Europe: +44 (0) 1344 708000

In other areas: 1 919 998 2000

Email: clinical.info@quintiles.com

> quintiles.com/biotech

