

Case Study

Oversight Monitoring Success

A biopharmaceutical company engaged Worldwide Flex to provide appropriate and impartial oversight monitoring for several studies. Such services can help to prevent a sponsor from receiving findings during U.S. FDA audits and in particular any from the FDA Form 483.

Worldwide Flex also supported this client with safety resources, so it was a natural progression for us to provide oversight management capabilities. To be prepared for the regulatory inspection, Worldwide Flex put ourselves in the shoes of an auditor by initially reviewing compliance on the work of the contract research organization hired by the client. Our oversight management proved successful – the FDA audit had no findings.



The Challenge

A longtime client working in the central nervous system area approached Worldwide Flex with the need for oversight monitoring of the work clinical research associates and a contract research organization were doing. Additionally, the client didn't have a template for the work that was needed and required assistance finding members to hire.



The Solution

No detail was too small for us. Worldwide Flex listened to what the client needed, developing templates for work that was needed and job descriptions to help find team members for the client. In doing so, we have been engaged in more than one study leading to an IND submission. From startup through Phase III, a Worldwide Flex team built an entire oversight monitoring plan and developed the standard operating procedures, and the oversight monitoring team and the clinical oversight monitoring plans. The team collaborated with the client on the report templates. Our global presence supported the client with five clinical trials with sites in the U.S., Europe, and Asia-Pacific.



The Outcome

Worldwide Flex developed a collaborative, flexible global program with the client, which enabled the client to enter Asia-Pacific, in addition to the existing European countries. During a clinical trial audit, one of the Worldwide Flex oversight monitors was complimented on a tracker for site readiness she had developed. In addition, the oversight monitoring proved so successful that the client went through an FDA audit that had zero findings.

Let's talk about how our personalized approach, development expertise, and global resources make us a strong partner for your development program.

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