FSP CASE STUDY

A STRATEGIC SITUATIONAL OVERVIEW
OF AN FSP ACHIEVEMENT

OVERSIGHT MONITORING FOR BIOPHARMA COMPANY

Orbis Clinical's FSP solution, OC Link, implemented oversight monitoring in a biopharma company program that was already deep in development.

SPONSOR'S CHALLENGE

The biopharmaceutical company received FDA inspection findings on lack of Sponsor oversight, and requested an FSP to implement oversight. At the time the program was in Phase 3, and already deep in enrollment.

SOLUTIONS DEPLOYED

Orbis Clinical provided a team of Clinical Oversight Leads

Fully designed and implemented a program infrastructure (plans, processes, templates) including communication of preferred CRO and sites

Implemented a Clinical Trial Management System (CTMS) customized for oversight visit reports and trend reporting

Conducted oversight visits at all sites and with all CRAs with patients for interim analysis

Identification of monitoring/ site trends and process for CRO resolution

RESULTS ACHIEVED

- Orbis Clinical customized Oversight Monitoring FSP required on all critical programs – a total of nine studies across US
- FDA/EMEA joint inspection with zero findings on Sponsor oversight
- No findings on the oversight process, leaving inspectors "very impressed on the oversight process"
- No critical/major findings at sites with oversight
- Sponsor implementing Orbis Clinical's FSP oversight process on all studies

Find out how Orbis Clinical's FSP Solution,
OC Link, can help you!

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