



# Bioclinica Submits Periodic Adverse Drug Experience Reports (PADERs) for a Multinational Specialty Pharmaceutical Company

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## Introduction

Aggregate reporting is a vital tool to monitor the benefit/risk balance throughout a medicinal product's lifecycle. The timeline, frequency and exact type of aggregate report required for submission vary amongst the drug regulatory agencies worldwide. In addition to the submission of individual case safety reports, companies are required to periodically review cumulative safety information from various sources, including clinical trial results and spontaneous cases, and submit any findings as aggregate reports to regulators. One type of post-marketing aggregate report is the Periodic Adverse Drug Experience Report (PADER) in the US. The FDA requires PADER submission quarterly for the first 3 years following the US approval date and annually thereafter and mandates specific information in the reports.

## Situation

A multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, gastrointestinal disorders, ophthalmology, neurology and branded generics was using another vendor for pharmacovigilance (PV) services. Due to ongoing quality issues, poor communication and poor project governance with their current vendor, the company approached Bioclinica for PV services, including aggregate reporting, focusing specifically on PADERs.

## Solution

Recognizing the company's urgent situation, during the one-month period between their selection as the preferred vendor and contract signing, Bioclinica gathered a dedicated project team of 15 expert resources in aggregate reporting based at the Bioclinica campus in Mysore, India. Each of the team members completed customized training and passed a rigorous evaluation to ensure familiarity with the company systems and processes.

Given the persistent issues with their existing vendor, the company opted for an immediate, rather than staggered, handover to Bioclinica. Because Bioclinica recognized the company's situation and relative uncertainty of the project, the scope of work at project initiation was flexible. Within days of contract signing, company representatives arrived at the Bioclinica delivery center in India to oversee the preparation and ensure a smooth transition. The company worked closely with the Bioclinica team to provide safety information for each PADER. Complex PADERs were discussed during a weekly call between the teams.

Although a team of 15 experts for aggregate reporting was deemed adequate to handle the estimated monthly volume during the scoping phase, a backlog of over 60 reports was identified at project initiation. Within three months after project initiation, Bioclinica produced over 120 reports (primarily PADERs), eliminating the backlog and ensuring all reports were completed ahead of schedule.

The Project Planning Checklist developed by Bioclinica included the planning activities that needed to be completed, and it was also used to track project activities that were finished, reviewed and/or signed off to help move the project into the execution phase. Weekly meetings were held to discuss the project status.



Bioclinica also collaborated with the company to audit existing processes, leading to the standardization of internal SOPs to achieve the desired quality levels.

### Outcomes

Two months after project initiation, Bioclinica had significantly improved the overall quality rates and radically changed the company's systems and process.

The quality of the PADER reports has been consistently maintained above the service level agreement (SLA) of 95% since project initiation in 2016, and the trend is increasing in 2018. The highest quality level (100%) was observed in October 2017. The reports have also been delivered on time to the company for review, resulting in an overall turnaround time of 100%. Over 200 high-quality, on-time PADER reports were prepared annually for two consecutive years.

The company recognizes Bioclinica's expertise and trusts the team to deliver on their promises. This has led to contract renewal for an extended partnership, as well as additional contracts on Pharmacovigilance activities.

### Summary

Submission of PADERs to the FDA is required during post-marketing drug safety surveillance. Instill confidence in your results and regulatory submissions by partnering with an experienced partner.

**Bioclinica** is a global life sciences solution provider that utilizes science and technology to bring clarity to clinical trials – helping companies to develop new life-improving therapies more efficiently and safely. Successful clinical trials require the ability to see key details and uncover hidden insights, and Bioclinica's hundreds of experienced scientific, medical, and domain experts bring unmatched insight across the development lifecycle, from the initial protocol to post-approval. The company's thousands of employees serve more than 400 pharmaceutical, biotechnology and device organizations – including all of the top 20 biopharmaceutical companies and leading CROs – through a network of offices in the U.S., Europe, and Asia.