

MEDICAL INFORMATION EXPERTISE

Expedited Medical Information Services Set-Up to Meet Tight Clinical Trial Timeframes

PrimeVigilance demonstrates its expertise by completing a **Medical Information project set-up in 3 business days**. This case study highlights seamless collaboration to ensure regulatory compliance and timely support for a client's clinical trial with multiple medical devices.



Challenge

A client approached PrimeVigilance for urgent support in managing device-related adverse event (AE) reporting for a clinical trial using three different medical devices. The key challenge was meeting a tight deadline, requiring PrimeVigilance to set up a fully operational Medical Information service in just 3 business days.



LOCATION
South Africa

**KEY TEAMS INVOLVED**

Medical Information, Pharmacovigilance,
Contracts, IT, Regulatory Intelligence

Approach

PrimeVigilance quickly assembled a multidisciplinary team from Contracts, Pharmacovigilance, Medical Information, and IT departments. Key steps included:

**Communication**

A kick-off meeting was held immediately after contract signing to ensure smooth collaboration and rapid decision-making.

**Process Development**

Teams quickly drafted process documents and conducted necessary trainings to meet the trial's technical and regulatory requirements.

**System Configuration**

The Medical Information database was configured ahead of schedule, and email mailboxes were set up to manage incoming AE reports.

**Regulatory Compliance**

Given the trial location in South Africa, the PV and Regulatory teams ensured full compliance with local regulations.

Result

PrimeVigilance successfully completed the service set-up within the 3-day timeframe, allowing the trial to start as planned and avoiding delays. The client, highly satisfied with the service, later expanded the scope to include reporting of Product Quality Complaints for the devices.

PrimeVigilance demonstrated its commitment to delivering timely, expert solutions. Through seamless collaboration, regulatory compliance, and efficient service delivery, the company ensured the client's trial proceeded smoothly, reinforcing their role as a trusted partner across all stages of product development.

Patient Safety Without Compromise

Global, integrated MI & PV systems for intelligent processing, auto reconciliation, and data insights.