CASE STUDY

PRECLARUS®: USING THE PATIENT DATA DASHBOARD TO IMPACT PATIENT SAFETY

BACKGROUND

While conducting Phase III studies in multiple indications for an antibiotic, PPD medical monitors observed that an adverse event was occurring at an unexpected frequency. Using the Preclarus® patient data dashboard, medical monitors were able to quickly and efficiently review data across multiple studies and indications to identify trends and ultimately assess whether the finding represented a potential safety signal.

OBJECTIVE

To utilize the Preclarus patient data dashboard to efficiently review cases of an adverse event observed at an unexpected high frequency and assess whether it could be attributed to the drug or associated with the disease under study.

CHALLENGES

Because the study involved multiple indications, a large and disparate data set needed to be quickly analyzed to ensure the safety of patients.

STRATEGY

To determine the significance of the unexpected frequency of the adverse events and, in order to ensure patient safety in the trial, medical monitors used the Preclarus patient data dashboard to review and analyze study data. Data sets from five studies and three indications were reviewed individually and in aggregate. The patient data dashboard enabled the medical monitors to integrate patient medical history, lab results, study drug dosing and concomitant medications in a chronologically organized format to efficiently assess possible commonalities and trends.

RESULTS

Through the efficient analysis enabled by the patient data dashboard, medical monitors were able to quickly determine early in the program that the adverse event was associated with the patients' underlying conditions and unlikely due to the investigational product. Using the dashboard eliminated the need for manual data collection and analysis, a time-consuming process that would have resulted in a longer timeline that could have potential safety concerns. The way in which the data was integrated within the dashboard allowed monitors to conduct a detailed review, resulting in a deeper analysis that led to the determination of the root cause of the adverse events.

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