Clinical Hold Avoided: Predictive Analytics Uncovered Concomitant Medication Dosing Risks Linked to Pancreatitis

A global biopharmaceutical company partnered with Prevail InfoWorks to strengthen their patient safety oversight across a late-phase clinical trial. While routine safety monitoring processes were in place, the sponsor sought early visibility into potential emerging clinical risks hidden within large volumes of study data.

During the study, a participant developed acute pancreatitis and was hospitalized, prompting a standard safety investigation. Initial reviews focused on the investigational treatment. However, traditional review methods struggled to efficiently assess the complex interplay between concomitant medications (ConMeds), dosing patterns, laboratory values, and patient outcomes across the entire study population.

The sponsor needed to determine whether the event represented an isolated case or an emerging trend, if concomitant medication dosing practices contributed to the pancreatitis event, and whether other participants might be at risk before additional adverse events occurred. Prevail InfoWorks already integrated the EDC data, the labs data, and the safety database data into a central repository, making it easy to identify across multiple clinical systems. Dosing patterns were automatically evaluated within Prevail's platform to identify correlations that would have been near-impossible to detect through manual review alone.

The investigation determined that the acute pancreatitis event was associated with a mis-dosed concomitant medication regimen that created a heightened risk profile for the affected participant. More importantly, the analytics did not stop at the initial case. Using the dosing pattern associated with the pancreatitis event as a reference model, Prevail InfoWorks analyzed the remaining study population and proactively identified 10 additional patients out of a cohort of 80 participants exhibiting comparable risk indicators. These participants had not yet experienced pancreatitis or other significant adverse events, but the data indicated they were on a trajectory akin to the initial patient's.

The sponsor and clinical teams were alerted immediately. Following an intervention, no additional pancreatitis cases were reported among the identified high-risk patients, clinical teams gained greater visibility into medication-related risk factors, and study monitoring shifted from reactive event investigation to proactive risk prevention. The project demonstrated how advanced analytics can extend beyond identifying the cause of an adverse event, to predicting where similar events may occur next. By uncovering the relationship between concomitant medication mis-dosing and pancreatitis, Prevail InfoWorks helped the sponsor prevent potential future patient harm, improve study oversight, and take corrective action before additional adverse events occurred.