Automated Clinical Trial Monitoring Workflows Make a Lean Team More Efficient

The Challenge: Burdensome Manual Letter and Report Creation

Until 2019, Enterin's clinical monitoring team manually created reports, confirmation letters, and follow-up letters. "Generating the letters and reports was cumbersome, and took 5-6 hours a week away from site monitoring," says Lisa Lutz, senior manager for clinical monitoring at Enterin. Personnel spent more time manually tracking site visits on a spreadsheet.

To increase efficiency, Enterin wanted to automate the generation of letters and reports, automatically notify clinical research associates (CRAs) and other stakeholders when site visits were due, and make it easier to share data with senior leadership and site managers.

The Solution: Medidata Rave CTMS

Enterin streamlined its clinical monitoring workflow with Medidata Rave CTMS (Clinical Trial Management System), a cloud-based solution for end-to-end trial management. The company immediately saw the value of Rave CTMS for issue management and site monitoring activities. During site visits, CRAs quickly record issues by selecting the appropriate checkboxes. "Issues and protocol deviations flow right into monitoring reports and follow-up letters, so stakeholders can quickly and easily see open items," Lutz says. "Rave CTMS is quite a time saver, and we're now creating reports in an hour or less."

In addition to Rave CTMS, Enterin uses Medidata's Rave eTMF (electronic Trial Master File) to create a single source of truth for all clinical trial documents. Reports and letters are automatically uploaded as soon as they are completed, so Enterin staff always know where to find them.

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Lisa Lutz
Senior Manager for Clinical Monitoring, Enterin

Value

- Time savings from automated report and letter generation
- Site-visit reminders based on activities and site history
- Support for remote source data verification during pandemic

Faster Report Turnaround

Enterin's clinical monitoring team now has a complete audit trail: report submission, review, revisions, and finalization. "I log into Rave CTMS to review CRA reports, and can make comments and questions directly in the report instead of sending it in an email," Lutz says. "Seeing the question in context, and not having to jump from an email to CTMS, helps CRAs answer sooner for faster report turnaround." The clinical monitoring team saves more time by not having to create presentations for Enterin's medical monitor, CEO, and clinical operations director. Instead, they generate reports with a few clicks in the Medidata CTMS dashboard.

Risk-Based Site Management

Instead of relying on spreadsheets to schedule site visits, CRAs now receive automated reminders based on activity triggers and Enterin's history with that site. Newer sites, for instance, are scheduled for more frequent visits.

With a glance at the Rave CTMS dashboard, the clinical monitoring team can review each site's visit schedule, last visit, issues, and the timetable for resolution of these issues. Managers can also view activities by CRA. "I can quickly see how many days it took each CRA to submit monitoring reports, how long an issue had been open, and whether we were in compliance with our standard operating procedures and monitoring plan," Lutz says. For transparency, Enterin gives site managers their own logins so they can see their site's data.

Smooth Transition to Remote Processes During Pandemic

During the COVID-19 pandemic, Enterin shifted to remote source data verification. The clinical monitoring team modified the Rave CTMS report templates to include remote monitoring visits, new questions, and new deviations such as out-of-window visits or missed procedures because subjects decided to stay home. Rave CTMS reports provide an easy way to share COVID-19 metrics with Enterin's leadership team so they can see how the pandemic is affecting the trial.

"By automating manual workflow and bringing all of our data together, Medidata CTMS has streamlined our entire clinical trial management lifecycle," Lutz says. "The less time we spend writing letters and looking for documents, the more time we have for activities that make trials successful—like collecting high-quality data and looking out for participants' safety."

ABOUT ENTERIN

Enterin is pioneering the medical community's understanding of the link between infections, dysfunction of enteric nervous system (ENS) of the gut, and the early onset and chronic progression of neurodegenerative disease. The long-term mission: become the world leader in developing pharmaceutical therapies that repair the gut-brain axis