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Small Biotechs, Big Safety Data Responsibility

As small drug developers take over more of the early-phase innovation, vendors emerge to fill the big safety data gap

By Suz Redfearn

It used to be relatively straightforward to aggregate all safety data from a compound's trials and send it to the FDA annually, as required. As the sponsor, you either had the data within easy reach in your files, or the one or two CROs you'd outsourced to could easily pull it together. It was simple.

But that was then. This is now.

Now, clinical research is awash in big, unwieldy data, and studies on one compound often have multiple endpoints across multiple protocols. Also, more often than not, the studies have been outsourced to several CROs, each of which uses different databases with different data standards and different coding.

Now, when it's time to send in that annual safety report for a compound in trials, a sponsor can become downright flummoxed — especially so if they are a small biotech, which is where many of the industry's promising compounds now originate.

"So many of these companies with new compounds are now just a dream and a team," said James Bannon, president and CEO of drug safety and pharmacovigilance company WCG Vigilare. "They don't have the same safety infrastructure as the big pharma companies and they can't divert large portions of their money away from their development projects in order to build out a safety department."

Added Bannon, "And to go back and gather all that safety data from all those different sources, can for a company like that be a major" corporate chore.

Or worse. For some, it's a nightmare wherein no one on the small, overworked team even remembers where all the data are or where to look, said Bannon.

Vigilare, he said, jumped into the market in 2014 to help these fledgling companies as safety-focused executives began seeing the shift to innovative compounds coming from small shops rather than big pharma. He added that big pharma now waits and swoops in to buy promising compounds when they're further down the pipeline.

Small drug developers can get so panicked about the regulatory requirements around safety that they reflexively run out and buy very expensive software that they have no idea how to use, said Angela Pitwood, vice president of Vigilare, formerly a pharmacovigilance exec at Pfizer. "They may call us and say, 'We already bought the million-dollar software. Can you help us?'" But by then, it may be too late, unless the software provider will take it back, she said.

The sweet spot for outsourcing the safety data burden to a company like Vigilare, said Bannon, is near the end of the compound's phase II trials, as the developer is gearing up for phase III and poised to potentially get involved with many CROs. At that point, a safety company like Vigilare can come in and bring a solution that "hovers above individual protocols," said Pitwood, with all safety data from all trials across many compounds saved in one place, since capture is begun early in the development process.

A compound's move into phase III is the point of no return for a sponsor company's easy control of the safety data, said Bannon. "The larger the datasets are, the harder it is to combine and ultimately analyze, and the more difficult it is to meet the FDA reporting requirement deadline," he said.

By partnering with a safety company, a small biotech can move more quickly through the development process, unburdened by demands to swim backward into the data to amass reports the FDA wants to see, Bannon said.

Pitwood said she thinks the increased uptake of such services that she and Bannon are seeing now will naturally lead to more companies outsourcing safety solutions even earlier in the development process, and reaping benefits that go beyond convenient aggregation of data for the FDA. Those include blending drug safety into earlier development phases so a sponsor is not just having drug safety looked at by clinical, but can use safety data for forecasting, said Pitwood.

"When companies do that, instead of just looking at what they're seeing, we help them look at what they might expect to see, then plan for that," said Pitwood. "Early adoption like this allows the safety vendor to examine what they're developing from an epidemiological perspective, with a group of people who have followed the product all the way through and are able to get ahead of what issues may come up."