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On Site: Experts Offer Advice on Seeking Research Site Excellence in an Age of Complicated Protocols

Despite endless talk over the last decade of ways to make clinical trials shorter and simpler, trials have only gotten longer and more complicated.

What can those in the field do to stem the tide? At the MAGI Clinical Research Conference 2018 East in Arlington, VA, a panel of experts offered their prescriptions.

Develop standard operating procedures (SOPs) that work for you — not against you.

Many sponsors, CROs and sites have gotten out of control with their SOPs, creating procedures so strict or so layered and bureaucratic that they are very hard to work within, and in many cases they decrease efficiency and slow down trials, said Michael Koren, cardiologist, and CEO and medical director of the site group ENCORE Research.

Some SOPs may not even make sense, and in an attempt to be compliant, companies may create more problems, said Dawn Furey, VP and head of portfolio delivery operations at Janssen Pharmaceuticals.

"Sometimes at very large organizations, the reaction to each audit finding is another belt or suspender that's built into an SOP, and in the end, you have SOPs that are so long and burdensome, you can't figure out what they say," she said.

"A good SOP is structured so there's enough meat there so people understand what is expected of them, but not so much that it micromanages them," said Koren.

And if you're nervous that going more lax on the SOPs will bring confusion or noncompliance, look to the FDA for guidance, said Taryn Losch-Beridon, principal with NB2C Consulting, formerly VP of clinical development for Mallinckrodt Pharma.

"The guidances will tell you where you need to be rigorous and where you can't cut corners and you need to be conscientious about that, but you don't want to be overly restrictive about the process so that you lose the creativity," she said. "You want people to have some flexibility in how they do their job."

Hire well, train employees, and bend over backward to support them.

"We are not flipping burgers; this is a complicated industry," said Koren. "And the most difficult part of achieving excellence at our sites is having people stick with it long enough to have enough experience to understand what's going on."

That goes for coordinators and investigators alike, said Koren, adding that there's an assumption that because physicians understand medicine, they'll understand everything about conducting research, when it can take years to pick up the necessary nuances.

"They need to be able to jump from the world of the patients, where they're answering the clinical questions, to the world of the FDA, to the world of the sponsor, to the world of the coordinator and the monitor, who have their own dynamic going on," he said.

Sponsors, CROs need to spend more time supporting sites.

Losch-Beridon urged sponsors and CROs to try to get to know each site well, coming to understand where their strengths are and where their weaknesses lie, then offering them as much support as possible to strengthen weaknesses.

"Really get into what is it that makes this site tick," she said. "Is there an excellent investigator who understands the disease state, but has little GCP knowledge? Then what can we give to that site?"

Build quality management into your systems while they're still young.

Small companies take heed: your lack of infrastructure is a good thing. Losch-Beridon, who has spent part of her career at a small sponsor and part of it at a medium-sized one, said small companies are better positioned to create effective quality management systems.

"A lot more small organizations have quality dovetailed into their processes now," she said. "Quality was built into what we did — not bolted on," she said.

Once a company swells to have many employees and many SOPs, it's too late, so young companies should take full advantage of that.

Sponsors, be friendly, flexible, agile and open to investigator-driven ideas.

Sites, said Koren, have grown weary of working with sponsors who don't do the work at the feasibility stage to understand what's possible in recruiting for specific protocols. Sites much prefer to work with sponsors who are, instead, flexible about recruiting, eager to listen to investigators' ideas about recruitment – even if their ideas may not result in 100 perfect patients but instead may yield one patient and may help the sponsor put in place new systems that will help recruitment on other studies, said Koren.

So many sponsors these days are fixated on finding only that elusive perfect patient who satisfies 10 inclusion criteria and 20 exclusion criteria, said Koren. The problem, though, is that that perfect patient just doesn't exist.

Work to ensure consistency among all sites working on the same study.

Said Losch-Beridon, site consistency is one of the biggest issues facing those working in clinical development — from variability in how different people at one site are interpreting the protocol, to variances in how different types of sites (academic, community practice) are enrolling patients to the same study.

"Everybody touches the data — everybody — from the data managers to the CRAs to the sites," she said. "It's just so critical to make sure there's a line there so you're not seeing disparate results either by region or by site type."

If you standardize how every site is approaching the same trial, that brings efficiency, better data quality, fewer fires to put out, and faster trials.

Said Furey, despite all the metrics used to measure excellence in the industry, ultimately excellence is in the eye of the beholder.

"I don't think excellence is a prescription. I think excellence is a perception," she said. "It has a lot to do with how you satisfy your stakeholders — your partners, your patients, your sites, and how your performance is perceived. You have to define the criteria for what excellence is and how you get your feedback from your stakeholders. How you respond with that is absolutely critical in the way you define your path forward."

— Suz Redfearn

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