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FDA's Proposed Single IRB Mandate Could Streamline Clinical Trials

By Jane Anderson

Institutions that take steps now to comply with the Food and Drug Administration's (FDA) proposed rule aligning FDA institutional review board (IRB) regulations with the Common Rule will likely see benefits in terms of streamlined processes and improved activation timelines, experts said.

Sandy Smith, senior vice president, clinical solutions and strategic partnerships at WCG, told a webinar audience that FDA's proposed changes—released along with a second notice of proposed rulemaking (NPRM) on the same day in 2022[1] —will require institutions to make some changes but ultimately, those changes will be positive enough to warrant institutions moving forward prior to the rules being finalized.[2] WCG is a consulting firm that can be contracted to serve as a single IRB; it also offers related clinical trial services.

"We know that it will make it much easier for the [trial] sponsor, but we also believe it's going to be easier for the sites as well," said Smith, who has stood up and managed local IRBs both for community hospitals and a large site management organization. "Overall, we do believe that this will add efficiencies; it will reduce activation timelines and hopefully be easier for your team members. But there's work in working out all of the workflows."

The May 2 WCG webinar covered two FDA NPRMs: the NPRM on "cooperative research"—known as the single IRB requirement—and the NPRM on the protection of human subjects and IRBs. On the protection of human subjects NPRM, WCG speakers specifically focused on the part that deals with informed consent.

Trial Activation May Accelerate

As institutions anticipate the final FDA rules being published, they're approaching the NPRMs—particularly the proposed single IRB mandate—in different ways, Smith said. "Some are jumping on it more immediately and saying, 'This is likely going to come into fruition; therefore, how do we get this on our work plan and begin inputting timelines associated with it?' Other sites are kind of saying, 'Yep, we are aware of it, but we're just going to hang back a little longer because we've got a lot on our plates.'"

Smith told attendees that "clearly, we know there are challenges in maintaining your IRB—things like ensuring that you have the right expertise. Our clinical trials today are getting very, very complex. Just looking at all of the discussions about artificial intelligence and how that's going to weigh into clinical trials, ensuring that you have that level of expertise and knowledge is going to be critical. And I think the other challenge always is ensuring that your IRB members have been updated in providing education on the latest rules and regulations. So, this is not an appointment that's made lightly."

In fact, research sites have a lot on their plates with technology and other initiatives, Smith said. However, the NPRMs have the potential to positively impact activation timelines, and "clearly there isn't a single site that I speak with that doesn't refer to a process improvement or a laser focus on their activation timelines," she said.

Some sites are activating trials in less than 30 days, while others take "well beyond 300 days," Smith said. "And we know that IRB just fulfills one part of that process." Moving now to implement aspects of the NPRMs could positively impact the IRB component of the activation timeline.

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In addition, "we also hear a lot of angst about how [sites] can navigate their local requirements," Smith said. "I might suggest you take this as an opportunity to really back up and look at what your local requirements have been and pressure-test them. Are they really needed today? Maybe things were written into policy years ago that may not have as much emphasis today—particularly with the move to a central IRB. So, take that as an opportunity to really explore what those local requirements are before doing slight amendments and accommodating those within the workflows."

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