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IRB Experts Offer Advice for Changing Research Landscape

How to enter next research era

By Melinda Young

It is clear that clinical trials now exist in a different world from what researchers, IRBs, and sponsors experienced in 2019. The key challenges are how to restart clinical trials, how to return to in-person visits, and how to manage the growing number of studies related to COVID-19.

"Like many industries, the clinical trials industry is one that got very comfortable in its routines and patterns," says **David Borasky**, MPH, CIP, vice president of IRB compliance with WIRB-Copernicus Group (WCG) in Princeton, NJ.

"Even as ideas were coming out of various sectors of the industry to do things different ways, whether it was risk-based monitoring or remote and virtual clinical trials, people don't like change," Borasky explains. "It makes people nervous to do something in a different way, and that is often amplified when you're in a regulated environment because nobody wants to be the first one to do something new."

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The clinical trial industry knew in 2019 what was acceptable to regulators, and they largely stuck with the familiar. In 2020, the familiar disappeared in the wake of the pandemic.

"It has really changed the landscape of clinical trials," said **Suzanne Caruso**, vice president of clinical solutions with WCG. Caruso spoke about the realities of restarting clinical trials at a May 6 WCG web conference.

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"The impact on clinical trials has been really significant," Caruso explained. "We're now at more than 950 trials that have started in COVID research in 2020."

To imagine a post-COVID-19 future, IRBs and research organizations will need to assess what worked and what did not in the pre-COVID-19 research world, suggested **Ken Getz**, MBA, deputy director and professor at Tufts Center for the Study of Drug Development of Boston. Getz spoke about the future of clinical research at a WCG web conference on April 29.

"It's quite a challenge to attempt to take on and tackle imagining what the future might look like, knowing that each and every one of us has been formulating and reformulating a picture based on highly fluid conditions that we face at this time," said Getz, founder and board chair of the Center for Information and Study on Clinical Research Participation, and a member of the WCG board of advisors. "We look to the past to frame our thinking about imaginings for the future. What did the world look like in 2019 and Q1 of 2020, which seems like so long ago?"

For instance, studies were highly complex, and there was considerable fragmentation and poor coordination, Getz said.

"These relate to the high degree of customization, which drives inefficiency, cost, and poor performance, and have characterized protocol development for a long time," he explained.

The near past also featured high levels of risk aversion, limited regulatory clarity, and mixed — but improving — public and patient engagement, he said.

A look at clinical trial trends over the past decade shows a high growth in the endpoints and scope of protocols and data collection. "The number of primary endpoints has not risen dramatically, and the number of key secondary endpoints has not risen dramatically," he added. "But, there's an increase in the number of exploratory and miscellaneous endpoints."

Data collection, as well as the diversity of data, has increased dramatically, Getz said. For instance, protocols can collect data from case report forms, laboratories, smartphones, electronic clinical outcomes assessments, electronic medical records, mobile health, wearable devices, and social media.

Another trend is in the decline of the size of pivotal trials. "That's a function in all of the studies we now support that target rare diseases and stratify patient populations," Getz explained. "Complexity also is associated with higher numbers of protocol amendments. The No. 1 reason to amend protocols is to relax eligibility criteria because it's so difficult to find subject volunteers."

One of the more challenging trends involves study enrollment, which has declined over the past decade. "Nearly half of all investigative sites underenroll or fail to enroll a single patient," Getz said. "Regardless of the clinical research area, clinical trials are typically doubling their planned enrollment period."

In the post-pandemic clinical research world, there is an opportunity to reverse some of the negative trends. For example, protocol designs in 2021 likely will include even greater complexity and customization, but might be supported by flexible and scaled capabilities, including more machine learning and analytical approaches, Getz said.

IRBs and research organizations should expect more trials using virtual and remote approaches, now that sponsors have a broader sense of these capabilities, he said. There also will be broader use of hybrid clinical trials with remote and virtual elements, including self-administered procedures and diagnostic assessments. These changes will help fuel a shift away from urban settings and increase study participation in rural areas.

"We will have an increased use of collaborative designs and shared development risk," Getz noted. "We anticipate more preauthorized and conditional-use trials, where we'll support speed by relying on collecting data in real-world clinical care settings."

IRB and research staff can expect to see workplace attitudes change in the post-pandemic world, as well. For instance, there will be increased receptivity to remote interactions, Getz noted.

"More places are receptive to working from home now. There's growing awareness of colleagues and life balance as we come into homes in our remote interactions," he said.

Organizations and employees are developing greater empathy toward colleagues and work-life balance, and people are better prepared for these virtual and remote meetings. "We're getting better at shortening the amount of time we have to make decisions," Getz said.

Changes from the pandemic could lead to improved research recruitment as more people might enroll in studies that do not require as many in-person visits. This means rural participants would face fewer transportation barriers.

Although the research industry knew improvements in recruitment were needed, they were willing to accept the status quo and mitigate recruitment failure by increasing the number of research sites, Borasky says.

"With the pandemic, all of that turned on its ear," he adds.

Some studies will need to continue in-person visits. But many others can adjust those schedules and rely more on remote visits. "You won't see oncology studies in the home," Borasky says.

In-person activities are necessary for Phase I studies where participants receive the study drug and blood draws in rapid succession for pharmacokinetics, he adds.

"There always will be research studies that are very intensive and don't lend themselves to be done remotely because they involve a lot of interactions with subjects or procedures that require trained medical staff," Borasky explains.

But Phase III studies that are screening participants with monthly or quarterly visits to review changes can lend themselves well to remote work, he adds.

"There are a lot of assessments that don't require intensive oversight or inpatient hospitalization to get that done," Borasky says. "Those are often the big multisite clinical trials that take up a lot of time and have trouble recruiting and sustaining their enrollment."

During the later stages of the pandemic, when many parts of public life have resumed, IRBs and researchers will need to decide whether it is better to resume in-person visits or continue with remote visits.

"If you changed your methods to do remote activities, do these have any impact on the risks to human participants in the study?" Borasky says. "That's case by case."

Questions include:

- Is it unwise to send participants home with the study drug/device?
- What are the potential serious adverse events?
- Can risk of COVID-19 infection be safely reduced for in-person study visits?
- Should blood draws be performed in a commercial lab, or in the participant's home by a health professional?

"IRBs would want to know how safety issues are managed in a remote setup," Borasky says. "Regardless of the setting, criteria for IRB approval remain the same, although IRBs might have questions about the ability to do it remotely and practical concerns."

Independent IRBs often are more flexible because they serve multiple sites simultaneously and must maintain rosters of IRB members from a wide variety of backgrounds and geographic areas. Unlike academic or hospital IRBs, they do not rely on internal talent, Borasky explains.

Independent IRBs have remote work systems in place that were quickly implemented when work-at-home orders were made.

"We miss seeing each other, but the work goes on uninterrupted, and, I would say, seamlessly," Borasky says. "It was a good transition."

After going through the huge and abrupt remote work changes forced by the pandemic, all IRBs will have similar experience and systems in place.

It is possible that many of these systems — especially remote study visits and remote IRB meetings — will remain after the pandemic.

"It is entirely possible that for people stuck in old ways of thinking, the scales will fall from their eyes, and they'll say, 'We could have been doing this all along,'" Borasky says. ■

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