MEDTECH INSIGHT
CITELINE COMMERCIAL

03 Nov 2023 | **Analysis**

‘Resilient’ Trials: US FDA Wants To Apply COVID Lessons In Trial Design

by Michael McCaughan

The US FDA is not expecting sponsors to launch ‘pandemic-proof’ trials, but does want to see advance planning so that adaptations can be implemented for unexpected emergencies with ‘less burnout.’

The US Food & Drug Administration wants clinical trial designs to anticipate potential changes that might be necessary in the event of a public health emergency or natural disaster.

During an October workshop on mitigating clinical trial disruptions, Center for Biologics Evaluation & Research Deputy Director Celia Witten captured a key message from the discussion: “The goal is not to ensure that every trial is pandemic-proof, but to incorporate resilience into clinical trials.”

More broadly, FDA participants urged trial sponsors to move beyond cataloguing lessons learned from the COVID pandemic and instead focus on applying those lessons proactively when launching new trials. We are pivoting a little bit toward understanding and supporting implementation, not just developing policies,” to enable innovative approaches to trial conduct, Office of Medical Policy Director M. Khair ElZarrad said in summary remarks at the end of the workshop.

The workshop was co-hosted by FDA and the Clinical Trials Transformation Initiative and fulfills a directive of the 2022 FDA Omnibus Reform Act for the agency to convene a public meeting on the trial flexibilities adopted by FDA during the pandemic. (Also see "*Decentralized Clinical Trials: Quantifying Costs, Benefits Could Drive Adoption, Reduce Disruption*" - Pink Sheet, 31 Oct, 2023.)

While the meeting was a forum for feedback and experience from across the clinical trial community, FDA Deputy Commissioner Janet Woodcock set a tone early on that – at least from her perspective – the focus should be moving past “lessons learned” into actual changes in trial designs and planning.

“The successes and the challenges of the clinical trial ecosystem’s COVID response have been identified,” Woodcock declared. “We need to incorporate those best practices, some routinely and have some for an emergency. We also need to address those areas where we fell short and figure out ways we can shore up the resilience of the system so that we can deal better, with less burnout, frankly, in the next emergency that we face.”

“As we all know in hindsight, the pandemic posed a huge challenge for ongoing and needed clinical trials. And our ecosystem rose to that challenge,” Woodcock said.

However, “as I know from personal experience, this was a tough time. It required a huge amount of work across all the involved sectors. Everyone who works on clinical trials in one way, or another had to put in a huge amount of work to keep trials going and to implement new ones in the face of this pandemic.”

“Of course, any new disaster or emergency will pose new and different challenges, potentially, but hopefully, we can apply what we have learned and mitigate some of the pain in the next disaster or pandemic because we have experienced something and we have learned,” she said.

“Lessons learned run across the whole spectrum of the enterprise, from trial planning and regulatory requirements … through recruitment and consenting of patients, to trial conduct and follow up of people,” Woodcock continued. “We need to make sure these recommendations are not just put into a report and put on the shelf, but that we implement when practical as many of those as possible.”

Woodcock suggested three categories of changes to keep track of:

1. Innovations that clearly improve trial conduct and should become routine even outside emergencies;

2. Techniques that worked during COVID and may be useful in future emergencies but are not appropriate for routine use; and

3. Adaptations that did not work and should not be tried again.

“Some innovations were highly successful and can be used widely, even outside of an emergency setting,” she said, citing digital tools as a prime example. “Digital connectivity that had been explored in trial settings prior to the pandemic really went mainstream during the pandemic. And I think that was a good thing,” she said.

“Inventive and innovative ways to consent, to follow up people that had been experimental and

had been gingerly tried prior to the pandemic really became a routine, something that we could rely upon to deal with people who are potentially infected and infectious, yet needed medical care," she added. That message has already been carried forward into new draft guidance on "decentralized" trial techniques. (Also see "*FDA's Decentralized Trial Guidance: Investigator, Health Care Provider Demarcation Raises Questions*" - Pink Sheet, 24 Jul, 2023.)

Other changes worked for the emergency, but are not likely to be used routinely. They "are good enough for necessity, but not for ordinary business," Woodcock said.

Changes that "were too hard" or "took a little bit more shortcuts than people are comfortable with." But "they should be identified and kept in our back pockets ready for the next emergency when we knew they had been deployed successfully."

Finally, some changes "didn't work well. It is important to identify failures as well success, so we don't repeat our mistakes next time we have to deal with something."