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US FDA's Pazdur Wants Clinicians To Help Set Oncology Research Agenda

by Derrick Gingery

Oncology Center of Excellence director said clinical trial participation may increase if the research questions are 'significant to answer.'

The answer to increasing participation in oncology clinical trials may be improving the questions that studies are answering.

Despite decades of work and therapeutic improvement, cancer clinical trial participation still remains at about 5% of patients. Richard Pazdur, director of the US Food and Drug Administration's Oncology Center of Excellence, said during a 1 February webinar that better research questions could lead to more clinical trial participation, adding that OCE officials may gauge the most important unknowns about cancer treatment to inform the research agenda.

"We have an ongoing thing here we're thinking of doing is taking the common disease areas and asking clinicians what are the five basic questions that you want answered in the next five years so to speak," he said during a Conversations on Cancer event on therapeutic and regulatory innovation, which was sponsored by the OCE and European Medicines Agency. "The numbers usually come when the questions are significant to answer."

Pazdur said focusing on essential questions could help streamline the process, which is another idea OCE is pushing.

"Our point is like what's the essential question that you need answered and what's the quickest way of answering that question with the least amount of data that can be collected?" he said. "We really as an oncology community have made our lives somewhat too complicated and need to draw back and ask basic questions."

OCE created Project Pragmatica to make clinical trials more patient-friendly and efficient. In cases where long-approved cancer therapies are being used, the FDA may not require safety data

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collection because it is not necessary. (Also see "*Project Pragmatica: US FDA's OCE Initiative Aims To Encourage Simple Clinical Trials*" - Pink Sheet, 21 Nov, 2022.)

Pazdur said during the webinar that fellow regulators in Europe and Japan endorse the streamlining effort, as well as "how we could use really clinical trials that represent the real world rather than artificial patients that have all these eligibility criteria that will not reflect the patients that are ultimately going to use the drug."

Multiple efforts to improve clinical trial accessibility also are ongoing at the FDA and in industry. OCE is encouraging sponsors to expand trial eligibility requirements in part to increase participation. (Also see "*Oncology Clinical Trial Eligibility Expansion A Focus For US FDA; Sponsors Overcoming Initial Hesitation*" - Pink Sheet, 15 Apr, 2021.)

OCE's Project Equity program, which ensures trial data submitted on new oncology treatments reflects the demographics of the patients who will receive it, also is part of the effort. And new law now requires sponsors to submit diversity action plans as part of their trial design process. (Also see "*Clinical Trial Diversity Plans: Early Oncology Experience Shows More Work Needed, US FDA Says*" - Pink Sheet, 2 Dec, 2023.)

Encourage More Academic Trials, Professor Says

Edward Laane, assistant professor at the Tartu University Hematology-Oncology Clinic in Estonia, said during the webinar that many clinicians still wonder which treatments are best in certain situations. He said academic clinical trials can answer those types of questions, but few are available compared to industry-sponsored studies.

"It's important to keep academic trials also somehow into more focus because sometimes academia may be more precise questions or may be more burning questions than industry, which is really important for patients," he said.

Pazdur agreed, saying that regulators need to foster more independent clinical trials.

"They do answer different questions," he said. "Whereas much of the pharmaceutical activity are geared toward drug approvals, many times we have to ask clinically important questions about how different drugs may work together, what is the superiority of one regimen versus another regimen, and many times that's missing from pharmaceutical industry's

Could NIH Help US FDA Answer More Postmarketing Questions?

By Derrick Gingery

14 Feb 2024

FDA Commissioner Robert Califf said pharma should not be the sole entity handling postmarket research.

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clinical development plans."

Multipronged Clinical Trial Reform Efforts

Multiple FDA officials have called for clinical trial system reforms, including FDA Commissioner Robert Califf.

Califf has said the postmarketing evidence generation system needs to be improved (Also see "*Califf's Top Priorities For New Year: Misinformation And Evidence Generation*" - Pink Sheet, 1 Feb, 2024.), and has advocated for more trials to be conducted in the US. (Also see "*Califf Laments Shift To Ex-US Clinical Trials – As Well As Pace Of Reforms At Home*" - Pink Sheet, 12 Jan, 2023.)

Former Principal Deputy Commissioner Janet Woodcock also advocated for technology upgrades and increased use of novel trial designs. (Also see "*Janet Woodcock Retires From US FDA: 'I'm Trying To Tie Up All The Loose Ends'*" - Pink Sheet, 26 Jan, 2024.)

Other ideas could emerge from an FDA and National Cancer Institute "think tank" that aims to improve the clinical research system. (Also see "*US FDA, NCI Collaboration Deepens To Include Clinical Trial Innovation 'Think Tank'*" - Pink Sheet, 7 Dec, 2023.)