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The complexity of modern cancer treatments requires collaborative relationships between regulators, industry, academia, and patient advocates.

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Richard Pazdur, MD, Director of the Oncology Centre of Excellence (OCE) at the US Food and Drug Administration (FDA), leads the agency's efforts to streamline and modernize the regulation of cancer therapies. Since its creation in 2017, the OCE has become a hub for innovation, fostering collaboration across FDA centres, advancing global initiatives like Project Orbis, and integrating real-world evidence (RWE) into regulatory decision-making. In this conversation, Pazdur shares how the OCE balances rapid patient access with rigorous safety standards, navigates the challenges of increasingly global clinical trials, and partners with industry, academia, and patient communities to shape the future of oncology drug development.

What was the initial goal of adding such a centre within the larger FDA structure, and how does the OCE collaborate with other centres within the FDA?

The impetus for creating the OCE was really the changing field of oncology, requiring a regulatory environment more responsive to rapidly emerging scientific advances. When I joined the FDA 25 years ago, an oncology reviewer might work on an application for a breast cancer treatment one day and a lung cancer treatment another day. Over the years, we reorganized to create disease-specific teams and divisions that resemble how major cancer centres are organised. However, the

overall FDA structure continued to review oncology products across multiple Centres—drugs in CDER, biologics in CBER, and devices in CDRH. The OCE was formed in 2017 to expedite reviews through greater collaboration and coordinated reviews to ensure consistent regulatory approaches.

The Centre also enables us to develop specialized expertise in areas like paediatric oncology and rare cancers and innovate with many regulatory projects such as the Real-Time Oncology Review, Project Orbis, and others. We are also tasked with external outreach to patients with cancer and with various oncology organisations. To be effective, we must collaborate with stakeholders to develop discussions and conferences that will have an impact on drug regulation. These projects also contribute to the professional development of our review staff.

With oncology representing over 30 percent of yearly pharmaceutical activity and more than 10 new molecular entities approved annually in recent years, what are the biggest obstacles that the OCE and FDA face as a regulator while assessing safety and efficacy of cancer medicines today.

As regulators, we face the tension between providing rapid access to promising therapies and ensuring we have adequate evidence of benefit. What I try to impress upon our reviewers is to always keep the patient in mind. We don’t work for the companies who developed the drug or the academics involved in the clinical trials. We work for the patients. Patients with a life-threatening disease are more concerned about progress against the disease. They want to live longer, and they know this may mean they will need treatment with multiple drugs throughout their disease course. They are less concerned about what endpoint FDA uses or whether the approval was based on a single-arm study or a randomised controlled trial.

It’s particularly difficult in settings where randomized controlled trials may be challenging, such as in rare cancers or heavily pre-treated populations. Combination therapies also present challenges in determining individual drug contributions and overlapping toxicities. We’ve worked to address these and other situations through FDA guidance documents to assist drug sponsors with their development plans before they even file an application. And again, collaboration is key, as our staff write these guidance documents after thorough research and discussion with experts within the FDA and externally.

Since its initiation in May 2019, Project Orbis has been a significant initiative fostering international regulatory cooperation for oncology drug development. What have been the key success criteria for Project Orbis, and where do you see the initiative evolving in the coming years?

Project Orbis has exceeded our initial expectations in fostering global regulatory convergence. We've measured success through, first, the interest of the participating regulatory agencies in these discussions and enabling simultaneous submissions and reviews across the agencies. Second, Orbis is facilitating more consistent regulatory decisions internationally; and third, regulatory decisions in other regions are occurring earlier (Zosso-Pavic, 2024) which means patients may receive access to new cancer treatments faster in participating countries than in the past.

Also, it's a voluntary program for drug sponsors, so with 633 global applications for 79 oncology products, that indicates substantial industry engagement.

Looking ahead, our Project Orbis international partners recently expressed interest in expanding Orbis to other countries or to other therapeutic areas.

Emerging locations, especially China, have seen substantial growth in clinical trials with just over 7,000 total registered oncology trials in China in 2024 compared to 6,000 listed trials in the US according to the WHO International Clinical Trials Registry Platform. How is the FDA adapting to incorporate findings from these global studies into the drug approval processes?

Oncology drug development has become increasingly international over many decades, with the development of multiregional clinical trials as the gold standard, rather than data from a single country. These large trials allow us to assess safety and efficacy across various regions and countries to ensure consistency of results.

A growing number of trials are being conducted exclusively in China or with a significant enrollment from China. FDA has limited experience with some of these trial sites, but we recognize the importance of building confidence in the trial results from these research centres. The participation of more clinical research centres from China in multiregional trials will potentially provide this experience and allow us to analyze data from China in comparison to other sites and regions.

What are the key opportunities in coordinating multi-country trials as global markets become more integrated into the clinical research ecosystem?

FDA has had a longstanding expectation that clinical trial participants should be representative of the population that would use the drug once approved. Thus, patient representation in clinical trials conducted within US-based clinical trial sites as well as across the globe is encouraged. Approximately 20 percent of the participants in these large multiregional oncology trials are enrolled in the US. The US has a heterogeneous population and a sophisticated medical delivery system, and we need to have confidence that the data are generalizable to our population and medical practice.

Many countries in Asia, for example, Singapore, Taiwan, South Korea, have rapidly adopted global standards for oncology practice, with improved infrastructure for clinical trials and medical oncology training. There are large, state-of-the-art cancer centers and academic medical centers. With that increased capacity, over the past 20 years, many Asian countries have participated to a greater extent in multiregional clinical trials.

From a regulatory perspective, this presents tremendous opportunities for broad patient representation while potentially accelerating enrollment timelines. While we encourage comprehensive geographic representation in clinical trials, we must ensure that findings from these trials remain applicable to US patients.

The OCE has identified the integration of real-world data and evidence as a scientific area of interest. How is the FDA and OCE approaching the use of RWE to enhance the regulatory assessment of oncology products?

Oncology RWE is rapidly evolving, and our objective is to understand the appropriate potential uses of real-world data (RWD) for drug development that would increase patient access to effective therapies. We are focusing first on settings where traditional randomized controlled trials may be infeasible or where RWE can provide complementary insights.

OCE’s RWE Program has developed frameworks for the appropriate use of RWE. We developed a team of reviewers within each oncology division to work with review teams to look at RWE within specific drug applications. In addition, there’s a great deal of work within the FDA and across external stakeholder groups to work on the appropriate use of RWD for regulatory purposes. However, there are many methodological challenges, including patient population selection,

balancing prognostic factors, and data quality.

What is your message to the global life science community about the role of the OCE and FDA in shaping the future of cancer care?

The OCE is committed to being thoughtful partners in advancing cancer care while maintaining our fundamental responsibility to protect public health. We're continuously evolving our approaches and fostering international collaboration to meet the challenges of modern cancer drug development. We're striving to be more efficient and responsive while maintaining rigourous standards.

To the global life science community, I emphasize the importance of early and ongoing engagement with regulatory agencies. The complexity of modern cancer treatments requires collaborative relationships between regulators, industry, academia, and patient advocates. We encourage sponsors to engage with us early in drug development, to embrace innovative trial designs when appropriate, and to prioritize broad patient representation and global applicability in their development programmes.

Reference:

Zosso-Pavic M, Li Q, Atiek E, Wolfer A, Rohr UP. Effect of Project Orbis participation by the Swiss regulator on submission gaps, review times, and drug approval decisions between 2020 and 2022: a comparative analysis. Lancet Oncol. 2024 Jun;25(6):770-778. doi: 10.1016/S1470-2045(24)00158-X. Epub 2024 May 13. PMID: 38754450.

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