Accelerate Development of New Oncology Therapies with FDA's Project FrontRunner

The U.S. FDA Oncology Center of Excellence is continuing its push to improve drug access for patients with > 30 initiatives and projects underway in effort to help shape and transform cancer drug development. One such initiative is ***Project FrontRunner.***

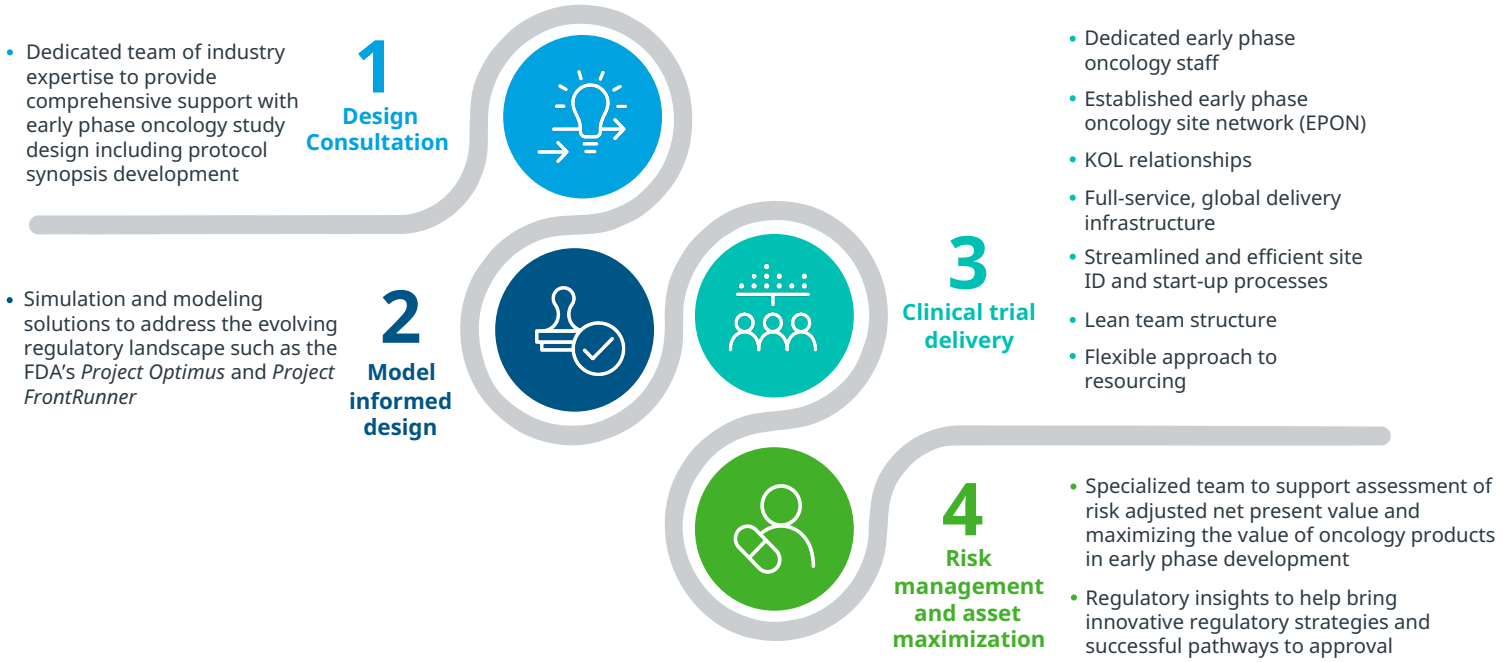
The FDA introduced *Project FrontRunner* to focus development on the need for new cancer drugs to be accessible to patients at earlier points in the cancer treatment pathway. Cancer drugs have traditionally been developed for patients who have already received multiple lines of therapy or have failed available treatment options. With this initiative, a larger patient population may benefit, addressing the significant number of newly diagnosed cancer patients each year.

The FDA has published draft guidance[1] for *Project FrontRunner,* outlining clinical trial considerations to support accelerated approval of oncology therapies in these earlier situations. The accelerated approval pathway is commonly used for approval of oncology drugs, and FDA is now expecting oncology drug developers to use randomized controlled trials more often. This increases the development burden associated with the accelerated approval pathway and may render this approach non-viable for many of the traditional relapsed/refractory or intolerant populations.

To address the burden, the FDA is encouraging drug developers to shift approaches to less heavily pretreated patients, earlier in the development process. Adjuvant or neo-adjuvant patient populations or consolidation therapy for an early line of treatment may be considered depending on the activity and safety profile of the drug. Additionally, the FDA has suggested that it may consider submissions based upon endpoints other than overall response rate, progression free survival or overall survival. Naturally all such approaches should be discussed in advance with the FDA and other appropriate regulatory bodies.

The evolving regulatory landscape brings challenges and opportunities for sponsors to consider to successfully bring new cancer drugs through development. While the FDA's *Project FrontRunner* guidance aims to expand access to a wider patient population, it represents a major shift in how drug developers should approach trial design.

IQVIA has enhanced solutions to address the challenges sponsors face in early phase oncology clinical development. These end-to-end solutions provide sponsors flexibility to adapt, make informed decisions quickly, and meet regulatory requirements.



By making intelligent connections, we bring innovation to the needs of today's oncology development. Leverage our expertise and capabilities for the dynamic regulatory landscape:

- Design and execute **sophisticated adaptive and novel trial designs bringing savings in cost and time**
- Build **body-of-benefit evidence** to support transition from late line therapy to first line or earlier lines of treatment
- Incorporate **dose optimization** in early phase oncology studies in combination with the opportunities associated with *Project FrontRunner*, including providing the necessary dose response modeling and trial design
- Identify which of the available development targets may be most suitable for a *Project FrontRunner* approach
- Integrate **biomarker strategies,** precision medicine expertise and endpoints selection early in development
- **Global laboratory services** from IQVIA Laboratories
- **Deep therapeutic expertise** to focus in on key questions, capture new ideas and opportunities, and take new approaches
- Extensive experience with **complex biostatistical planning and analysis**
- Expert **regulatory insights and advice** bringing innovative regulatory strategies to collaborate on successful regulatory pathways to market approval
- Design and deliver proactive **diversity action plans** for oncology clinical trials

Project FrontRunner is a paradigm shift in regulatory guidance that is moving oncology drug development into earlier stages of disease. The expectations from oncology drug developers will be to adapt their trial design, using fewer single-arm studies and instead shifting focus to randomized control trials that focus on development earlier in the cancer treatment pathway.

IQVIA is here to help you navigate the changing landscape and partner with you to bring novel therapies to cancer patients faster. Let's connect.

[1] Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics Guidance for Industry. FDA. March 2023

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CONTACT US
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