FRIENDS of CANCER RESEARCH

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Annual Meeting

Maximizing Data from Academic-Led Studies for Regulatory Decision-Making

EXECUTIVE SUMMARY

Clinical trials sponsored or conducted by academic investigators studying a drug's safety and/or efficacy, which we define broadly as "academic drug development trials" in this white paper, play an important role in advancing knowledge and improving patient care. These trials provide a unique opportunity to enhance our understanding of cancer, particularly by evaluating therapies in diverse patient populations, addressing pressing scientific questions, focusing on rare cancers, and generating data for regulatory purposes. While industry-sponsored trials are often the primary source of data for regulatory submissions, academic drug development trials can also contribute significantly to cancer therapy research and regulatory processes. This white paper emphasizes the importance of fostering collaboration between pharmaceutical companies and academic investigators to harness these benefits and optimize the use of academic drug development trial data for advancing cancer therapies.

Several factors impact the use of data from academic drug development trials, and thus this white paper aims to clarify these challenges and propose short-term and long-term strategies to overcome them. Key factors that can impact the ability to use data from academic drug development trials include insufficient early engagement with the U.S. Food and Drug Administration (FDA), heterogeneous data capture and monitoring requirements, and limited data access during trial execution, which can impact the data use and timelines for FDA submissions. Several proposals can enhance the use of data from academic drug development trials:

- Initiate early commitment and communication of registrational intent between industry partners and those conducting academic drug development clinical trials.
- Begin discussions early with the FDA regarding trial designs, analysis plans, endpoints, and data capture.
- Create a regulatory track for studies with potential registrational intent.
- Evaluate data sharing policies for studies with regulatory potential.
- Establish a streamlined process for submitting data to the FDA.

Leveraging data from academic drug development trials offers substantial opportunities to improve evidence generation and expedite patient access to innovative therapies. These opportunities can be realized through enhanced collaboration, aligning data collection with regulatory expectations, defining preferred data formats, and establishing guidelines for data sharing. Industry partners should consider long-term partnerships and increase support for these efforts. Implementing these strategies can streamline processes and ensure that academic drug development trials continue to play a meaningful role in advancing oncology drug development and patient care.

Click or access the full white paper with the QR code here:

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