Pharmaceuticals (includes Biologics & Drugs)

Expedited Programs to Support the Development and Approval of Products for Unmet Medical Needs

Wednesday, October 8, 2025 9:15 AM - 10:30 AM EST Location/Room: 317

Presenter(s)

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Regulators in different geographic regions have established programs aimed at supporting innovation by enhancing discussions with sponsors for effective drug development, reducing review time, or initiating the review process before all sections of the registration file have been completed or before confirmatory trials have been conducted.

This session will review programs available in the US, EU, and other regions, exploring how and when sponsors could incorporate these programs into their regulatory planning. The session will also include industry perspectives and case studies where applicable.

The session will cover programs designed to support products for serious conditions, as well as programs aimed at rare diseases. Among these expedited programs are the US Accelerated Approval pathway, Breakthrough Therapy designation, as well as pilot programs such as the Support for clinical Trials Advancing Rare disease Therapeutics (START) and Split real Time Application Review (STAR).

For the EU, this session will highlight acceleration programs such as PRIME and Conditional Marketing Authorization.

Learning Objectives:

- Expedited programs in the US that facilitate the development and approval of drugs and biological products for serious conditions or rare diseases.
- Expedited programs in the EU such as PRIME that support the development of medicines that target an unmet medical need.
- Summarizing how these different programs fit together in global, convergent regulatory strategies, and how they can also foster regulatory reliance.