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FDA's expedited testing and approval: Fast tracking drug approval-what does it take to qualify?

What does it take to qualify for the expedited FDA Drug approval? What is the breakthrough therapy designation application and how is it impacting the global drug development? In 2012, Congress created the breakthrough-therapy designation to expedite the testing and approval by the FDA, of medications with the potential to provide the substantial improvement over existing treatments. "Breakthrough Therapy Designation" is improved to hasten the growth and evaluation that are meant to treat the serious condition and introductory clinical proof indicates that the drug may reveal considerable increment over an available therapy on a clinically significant endpoint. To control whether the advancement over available therapy is considerable is a matter of discernment and depends on both the magnitude of the treatment effect, which could include the duration of effect and the elevation of an observed clinical outcome. In general, the primary clinical proof should show a clear advantage over available therapy. How the recent trends in globalization and the complexity of drug development have resulted in the possibility that expedited programs in one country may now influence drug development in another.

Biography

Aruna Dontabhaktuni is an internationally renowned pharmaceutical professional with 23 years of experience across all phases of drug development. She received her Pharmacy degree from Karnataka Pharmacy College, India and PhD from Long Island University, New York City. She is the founder and CEO of PharmaPro consulting, her company specializes in clinical pharmacology and regulatory submissions. She also serves on the scientific board for several pharmaceutical and biotech companies as a subject matter expert in clinical pharmacology. In her carrier, she has supported 30+ compounds from early, to late-stage of drug development, in oncology & immunology, other rare diseases including breakthrough therapy designations application for Olaratumab (LARTRUVO™). She has played the pivotal role in mentoring the next generation of scientists, thorough her managerial responsibilities. Her 50+ publications including posters, manuscripts and conference presentations as a keynote speaker at national and international conferences, are a clear testament to her achievements.

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