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FDA Expedited Drug Development Programs

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Drug Development is a complex and time consuming process. On an average, drug development can cost around $2.5 billion and on an average it takes more than 12 years for a drug to travel from discovery lab to patients [1]. With the intention of expediting the review process for those novel drugs that has the ability to treat unmet medical need and serious conditions, the Food and Drug Administration (FDA) has set up four expedited programs; Fast track, Breakthrough therapy, Accelerated approval, and Priority review.

Fast track designation can be requested by drug company if the new chemical entity is intended to treat serious conditions for which there are no viable treatment at the time of application. FDA owns the responsibility to make the determination, whether or not the novel drug has the characteristics to have a significant impact on survival, everyday functions, and probability of that condition turning into a more serious one if left untreated. Some examples of conditions that have fast track designations include AIDS, Alzheimers, heart failure and cancer. In general, any drug that is being developed for the treatment of unmet medical need would obtain fast track status, and in addition novel drugs that offers substantial superior efficacy may be also considered for Fast Track if the benefit of the novel drug is substantial in nature when compared to existing treatments [2].

Breakthrough therapy is designated for those drugs that already have preliminary clinical data demonstrating notable positive effect on a clinically significant endpoint when compared to the existing treatments. In this case, the FDA takes into account the enormity of the efficacy of the drug in question based on its effect on the clinical outcome demonstrating comprehensive advantage over available therapy [3].

FDA launched regulations for Accelerated approval in 1992. This regulation is particularly beneficial for those drugs that have the ability to treat serious conditions but there are no definitive clinical end points. Therefore, under accelerated approval program, a surrogate clinical end point will be considered for review of the efficacy of the drug. The onus remains on the drug company to provide scientific evidences to demonstrate that the surrogate end point is indeed a reliable marker to facilitate accurate prediction of clinical outcome [4].

Priority review designation offers the faster review of a new drug application by FDA. A timeline of approximately 12 month can brought down to less than 6 months with the help of priority review designation. The data package for priority review includes all of the data contained in the final new drug application. Once the drug is designated with a priority review status, the FDA ensures to provide sufficient resources to evaluate efficacy, advantages and impact of the novel drug [5].

The FDA expedited programs, "Priority", "Breakthrough", "Accelerated" or "Fast Track" is intended to facilitate faster decisions on drugs that has life changing effects and has a significant positive impact on global health, and the expedited programs do not compromise the quality of evidence necessary and the standard of review process.5 Although the expedited drug development and approval programs were intended to be limited in scope, there has been a continuous trend for increasing number of new molecular entities that are approved under these programs [6,7].

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