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Rate of drug approvals dips down: Nature Study

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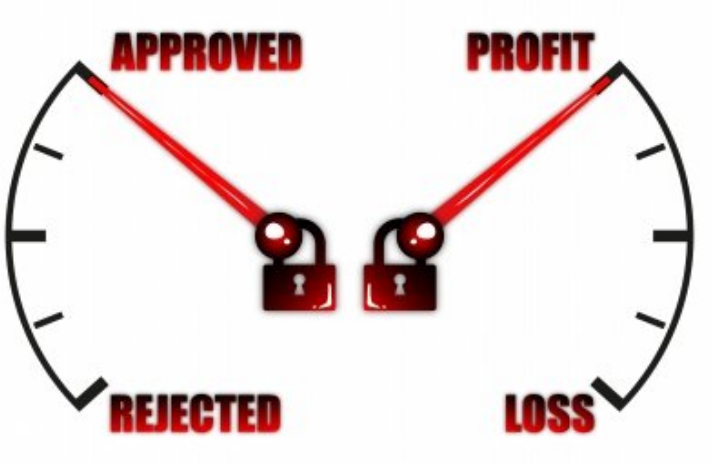

Singapore: Nature Biotechnology has published a peer-reviewed paper co-authored by the Biotechnology Industry Organization (BIO) Industry Analysis and BioMedTracker (BMT) highlighting results of a study showing that the overall success rate for drugs moving through clinical trials to FDA approval from late 2003 to the end of 2011 is near one in 10. Previous reports, taken from earlier years, showed the rate of drug approvals is one in five to one in six.

"This groundbreaking study highlights the depth and breadth of risk inherent in the drug development process more comprehensively than any other previous study," said Dave Thomas, Director of Industry and Research Analysis at BIO and one of the paper's lead authors. "Knowing more about the magnitude of risk can lead to smarter drug development as well as smarter investing."

The study builds on the findings from previous studies and uses a broader, deeper, and larger sample than previous reviews of clinical trials and approvals data using the BioMedTracker (BMT) proprietary database of close to 4,500 drugs and over 7,300 unique development paths.

"Having an up-to-date and detailed picture of clinical success rates, and ultimately how likely a drug is to be approved, is vital to our clients when making investment and business decisions. We believe that this study provides the market with an accurate and comprehensive picture of the relative difficulty of achieving product approval in the U.S.," remarked Michael Hay, Executive Vice President at Sagient Research. "Strikingly, oncology drugs have the toughest time making their way through the clinic, despite cancer being the most closely studied area in drug development. We are very pleased to be able to offer this analysis and provide an in-depth look at the issues facing the industry that lead to these lower rates."

Using clinical trial data from the past nine years, the analysis examines the most recent probability of success by treatment type, phase of development and therapeutic area. Before new therapies hit the market, they have to pass a number of hurdles - meeting regulatory thresholds for efficacy and safety as well as maintaining a competitive internal corporate profitability and marketability profile.

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Key findings from the study include:
Ã?Â¢Ã¢â??Â¬Ã?Â¢ The overall success rate from Phase I to FDA approval is nearly 10 percent. This number is comprised of lead and secondary indications.
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The BMT/BIO study examines the clinical Phase status of these development paths as of year-end 2003 through year-end 2011, which accounts for more than 5,800 Phase transitions. The study determines the percentage of drugs that advance to the next Phase of development versus those that are suspended and therefore the likelihood of a drug ultimately being approved by the FDA. The data spans all companies (Big Pharma and biotechnology, both public and private) conducting development on therapeutics for approval in the U.S.

The BMT/BIO analysis includes breakdowns by indication, disease group, size of company, molecule type, route of administration, New Molecular Entity (NME) versus Biologic versus non-NME. The data encompasses the most recent data available during a time in which FDA requirements for approval have been in flux. Included in the analysis is an in-depth look at FDA decisions and approval rates by FDA review number.