INNOVATION IN DRUG DEVELOPMENT: NAVIGATING THE OPTIONS

NEHI THE NETWORK FOR EXCELLENCE IN HEALTH INNOVATION

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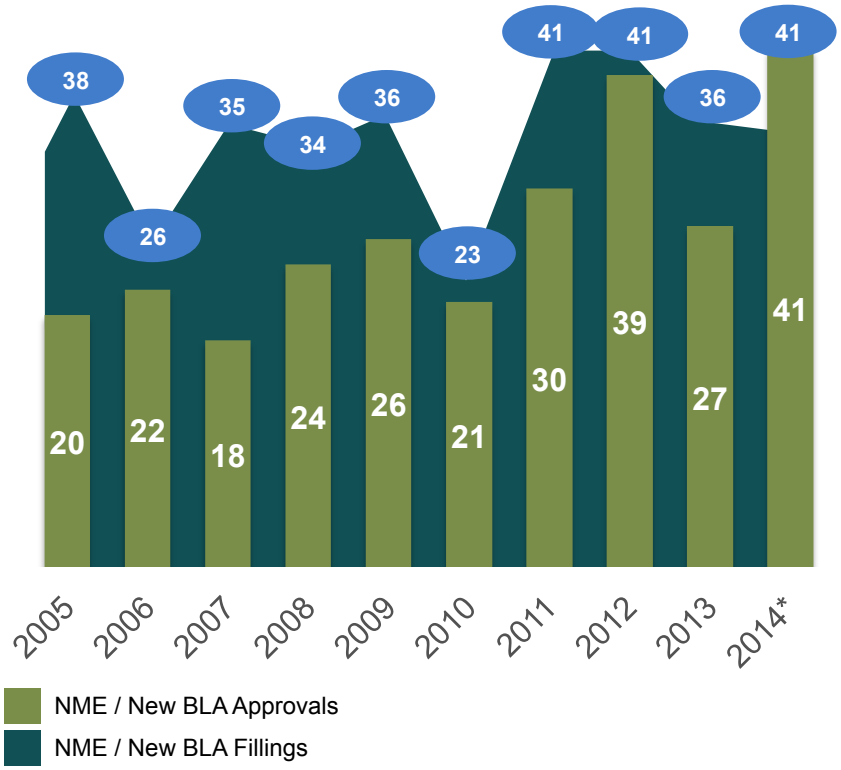
Innovation in Drug Development: Navigating the Options

IMPROVING R&D PRODUCTIVITY REMAINS THE KEY OPPORTUNITY FOR THE INDUSTRY



After decades of decline in R & D productivity, recent data shows gradual improvement; Leveraging accelerated pathways is one of the more viable means of continuing this trend

Sources:
U.S. Food and Drug Administration, Center for Drug Evaluation and Research "Novel New Drugs 2014 Summary," January 2015
Evaluate Pharma, BCG analysis

FDA PROVIDES A NUMBER OF ACCELERATED PATHWAYS

	Qualifications	Benefits
Fast track	• Serious condition AND • Demonstrate the potential to address unmet medical need OR • Designated as a QIDP	• Expedited development and review • Rolling review
Breakthrough therapy	• Serious condition AND • Substantial improvement over standard	• Expedited development and review • Rolling review • Guidance on efficient drug development • Organizational commitment
Accelerated approval	• Serious condition AND • Meaningful advantage over standard AND • Surrogate endpoint that is reasonably likely to predict clinical benefit	• Approval based on an effect on a surrogate or intermediate clinical endpoint
Priority review	• Serious condition AND • Improvement in safety or effectiveness OR • Designated as a QIDP OR • Priority review voucher	• Shorter clock for review of marketing application (6 month vs 10 month)
QIDP	• Serious condition AND • Antibacterial or antifungal drugs for human use	• Expedited development and review • Rolling review • Additional 5 year exclusivity
Orphan drug	• Serious condition AND • Rare medical condition AND • Lack of existing methods or treatment OR • Significant benefit to those affected by condition	• Tax incentives • Enhanced patent protection and marketing rights • Clinical research financial subsidization • Government assistance in development