

- In a 2004 white paper, the U.S. Food and Drug Administration (FDA) addressed the pipeline problem, stating “the current development path is becoming increasingly challenging, inefficient and costly” while “the number of new drug and biologic applications submitted to FDA has declined significantly” and “the costs of product development have soared.”
- The Tufts Center for the Study of Drug Development, in its ‘Outlook 2005’ paper, stated that the industry needs more than innovative technologies to deliver new treatments; it also needs productivity and quality enhancements to improve product pipelines. To do this, “drug developers must address big-picture issues such as creating more innovative R&D strategies.”

## **How can an integrated operations and business planning framework increase the productivity of an organisation’s R&D?**

Over the last few years, the pharmaceutical and biotechnology industries have experienced a reduction in development output, as measured by original new drug applications (NDAs) and biologics licence applications (BLAs). Simultaneously, the costs for bringing drug candidates through the development chain have increased, as has the pressure to deliver more value with limited resources. Industry leaders now recognise the necessity of operational efficiency to achieve a sustainable competitive advantage.

### **An industry forced to raise the bar on innovation**

Other factors driving the need for industry innovation include:

*Increased pressure to demonstrate continued revenue growth and increased shareholder value*

*Growing industry consolidation to accommodate economies of scale in research*

*Increased need for research and development to deliver more products with fewer resources and tighter budgets*

*Increased focus on accountability during the R&D process*

*Decreased probability of success (POS) of compounds in development because of the difficult targets pursued and earlier termination of unpromising compounds*

### **What should the industry consider?**

To successfully stay ahead of these trends, industry leaders recognise the value of an integrated operations and business planning framework. Organisations can use this framework to evaluate their operational readiness and address key business questions, such as:

*Do we have the resources for the development projects in our pipeline?*

*How do we allocate resources to meet our strategic objectives?*

*What programs will bring the most value to the organisation?*

*Should we in-license or out-license a programme? What are the associated costs and value of doing so?*

*If we increase a programme’s budget and resources, can we accelerate its timeline?*

*How accurate are our planning assumptions?*

*Do we have defined and realistic project plans? How well are we executing them?*

*How do we measure the throughput of our organisation relative to industry best practices?*

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## How can PwC help your organisation?

PwC helps clients answer these questions through the application of process-based, integrated operations and business planning methodologies.

Our service offering includes:

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*Business case definition — identifying the true business need and outlining the value proposition of a targeted solution*

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*Operating model development — defining, illustrating and re-engineering your organisation's functional and cross-functional processes*

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*Process-based requirements definition — developing clear, role-based requirements that drive tool development*

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*Standardised resource management — defining scalable resource planning models and product requirements for the development organisation*

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*Development chain management — linking the disparate planning requirements of project teams, clinical functions, regulatory functions, preclinical areas and operational functions*

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*Decision support framework — using analysis frameworks to assist with decisions regarding portfolio execution*

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*Portfolio visualisation and project reporting — synthesising planning and portfolio data to allow customised views for various stakeholders*

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*Implementation advice — leveraging industry-specific best practices to gain maximum value from enterprise tools*

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*Change management and communication — ensuring required behavioural changes to align the organisation, processes and systems for optimal results*

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By applying integrated operations and business planning, R&D organisations can produce a rational, achievable portfolio of projects while balancing operations in a matrixed environment.

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