Estimate the impact of time savings on your drug development program, asset value and financial company performance

An economic comparison of programmatic and transactional development models

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Executive Summary

Accelerating drug development is challenging yet critical to maximizing asset value. The faster you can reach key development milestones, the better positioned you are to efficiently maximize scarce resources and realize the full value of your asset with longer market exclusivity for you or your licensing partner. An important step toward accomplishing this most efficiently may surprise you: adopting the right drug development outsourcing model. Through considered value-based economic analysis, the benefit of a programmatic model over a transactional approach is made tangible and can result in millions of dollars in savings and accelerate development, positively impacting both your asset and company's financial performance.

Introduction

Value can be interpreted in different ways depending on your company's strategy or program objectives. It can be based on an individual asset or company net present value (NPV), revenue, company viability or liquidity: It can also be realized in different ways, such as in cost savings or efficiency.

In the drive for cost efficiency, a significant proportion of early drug development work has migrated from larger pharmaceutical to smaller biotech organizations in the last 10+ years. Questions still remain around the cost efficiency of this change. Indeed, according to recent analysis from Deloitte, "the average R&D cost to progress an asset from discovery to launch has remained flat for 2022-2023 at $2,284 million per asset" and "transformational change in R&D productivity is required to reverse the declining trends in returns across the biopharma industry and the ongoing challenge of continuing to deliver innovation to patients."[1] Through licensing and acquisitions, large pharma is utilizing the innovation and efficiency power of smaller biotechs to feed their pipelines. Biotech companies, therefore, hold a key role within the pharmaceutical sector as an innovation engine.[2,3]

To be nimble, improve efficiency and reduce fixed costs such as facilities and staffing, smaller companies are outsourcing drug development work to various research partners, leveraging their expertise and resources.[4-6] With this outsource strategy, it is estimated that 80% of companies are pursuing drug development as a series of independent transactions, utilizing several external vendors.[7] While this transactional approach offers some benefits (access to expertise, reduced fixed costs, etc.) it does not enable the greater opportunity to fully integrate a drug development program to save time and maximize asset value.

A newer, alternative strategy for drug developers is to adopt a programmatic model. Today, it is estimated that already 20% of the pharmaceutical industry has moved to a programmatic approach in which a single partner or a few limited partners prospectively plan, integrate and then optimally perform a set of predefined studies and services to support the development of a molecule. The result is increased flexibility, efficiency and enhanced insight—saving valuable time and maximizing asset value. The early adopters of the programmatic model **have realized up to 30% improvement in time savings on their new drug applications (NDAs).**[7]

A programmatic approach leverages program management principles and prospective planning to enable:

- **Reduction or elimination of "white space" or time gaps** between studies and development phases
- **Preservation of critical molecule knowledge** for easy transfer between different expert disciplines and across the phases of development
- **Parallel conduct** of studies to streamline the critical path of development
- **Maximized efficiencies** and removal of process, communication and other operational duplication
- **Additional time/value benefits**

This model is especially appealing to smaller organizations with limited funds and significant pressure to meet investor deadlines and stakeholder requirements.

For example, by successfully adhering to promised timeline commitments and development milestones, smaller organizations can gain access to additional funding.

Case scenario: Programmatic model

In this case scenario, the concept of the "time value of money" is transformed into a tangible value estimation that can be adjusted to facilitate outsourcing model comparisons.

Four key considerations are explored for comparing transactional and programmatic models and make economic conclusions:

- **Flexibility**: Determine what to outsource to align to your strategic objectives, meet key milestones and optimally save time
- **Cost**: Compare development models side by side to understand total cost differences, including both direct and indirect costs
- **Time**: Estimate how enhanced planning, communication and insights translate into time savings
- **Value**: Understand the impact of time savings on commercial launch timing, patent exclusivity and company/asset value for partnering discussions or financing evaluation

Flexibility

To plan your drug development program, it is important to start with your business and program strategic goals in mind. For example, do you plan to take your molecule to market or only to a key milestone, such as completion of first-in-human (FIH) studies, before licensing or selling your company or asset to another drug development organization? Your strategy will determine the type and timing of the studies you conduct: a series of individual studies, a program that enables progression to FIH or a comprehensive development plan leading to a NDA.

> "We are increasingly looking for our vendors to be more flexible, to accommodate our needs, to offer advanced methodologies such as adaptive design and to adapt to our strategy as it evolves."[8]

Nearly 70% of drug developers state that having the flexibility to run the studies they need, and a partner that can adjust to their specific priorities, is critical.[8]

When evaluating an outsourcing partner, find one that has the breadth and depth of experience to afford you the flexibility to design the package of studies that aligns to your business strategy and lays the foundation for a robust and efficient drug development program. Consideration should also be given to the number of outsourcing partners used. Reducing the number of partners can improve efficiency, communication and vendor management time and ultimately reduce time lag between studies.

Cost

Drug developers often expect that a transactional approach will be less costly when compared with a programmatic approach. This is based primarily on the ease of comparing quotes (direct costs). For example, comparing individual 13-week rat toxicology study quotes could save you $5K or $10K. However, when analyzing the impact of time on your overall program (i.e., direct and indirect costs for multiple studies), the indirect costs are often overlooked. In a recent survey of drug developers, 92% of respondents had not formally evaluated the indirect costs associated with a programmatic approach compared with a transactional model.[8]

> "We have compared the costs of transactional vs. programmatic outsourcing, but only informally. We haven't modeled exactly how much it really costs us."[5,8]

When evaluating the cost of a program, the programmatic model is typically found to be favorable to a transactional approach. Cost benefits can be derived from multiple sources, including potential volume or package pricing for a program versus individual studies. The more valuable (hidden) opportunities, however, are reduced startup time and the potential to reduce the need to add internal support. This presents an opportunity to reallocate internal resources to other critical efforts, such as finding the right licensing partner or securing additional rounds of investor funds for a biotech company.

To best evaluate total programmatic cost, it is important to consider the following:

- **Volume/program packages:** the impact of volume or package pricing for a programmatic model
- **Internal resource planning:** the indirect costs associated with utilizing a programmatic versus transactional approach to drug development

It has been found that between 2 and 10 internal headcounts[1] or full-time equivalents (FTEs) are necessary to identify, qualify, evaluate, select and project manage disparate vendors in a transactional model. However, it is estimated that the FTE may be reduced by more than 50%[9] under a programmatic approach for a comprehensive developmental program.

An economic analysis of programmatic approach could yield a 50% reduction in FTE required and significant associated cost saving versus a transactional model: potentially millions over the course of a complete development program.

Cost Analysis

	Transactional Model		Programmatic Model		Savings
Total (Direct + Indirect)	$10,511,773	-	$7,417,434	=	$3,094,339
Net Direct	$4,886,773	-	$4,642,434	=	$244,339
Net Indirect	$5,625,000	-	$2,775,000	=	$2,850,000

In our case scenario, outsourcing a full, critical-path developmental program for a small molecule under a programmatic model reduces internal FTE requirements dramatically. Assuming a conservative, 50% reduction in internal FTEs, indirect FTE cost savings can tally into the millions over the duration of the program.[9] Reducing FTE requirements can also free valuable resources to work on other programs or leading critical business efforts.

Each drug development program is unique. With a complete analysis, you can determine how resourcing levels impact your development costs both directly and indirectly and between key development milestones.

Time

Although challenging, minimizing development time is key for maximizing asset value. Each day added to a development plan diminishes the value for licensing or selling your molecule due to reductions in potential product revenue and market exclusivity. Small delays can accumulate into a significant extension in development time and can equate to 1.5 to 2 years of delay during the course of a full development program.[8]

A programmatic model improves communication between expert groups, adds insight and preserves program and molecule knowledge, all of which saves time versus a transactional approach.

> "How much time did we 'lose' in the development of our molecule? I'd say almost 2 years over the course of the program."[8]

- **Improved communication:** Consider the time it takes for internal communication among project team members, you and a single development partner. This dramatically increases with multiple vendors supporting a program and adds a heightened dimension of risk for miscommunication.
- **Greater foresight:** Clear and early visibility to arising data and study results combined with continuous planning throughout the full range of your services enables the development team to address potential issues before they arise. Program/molecule knowledge is preserved and can be communicated in context.
- **Speed:** Improved communication, planning and foresight enables an accelerated development program. This can translate into months and even years of time savings from lead candidate selection through to clinical proof of concept (PoC).

Value

The benefits of cost savings, faster progress through milestones and a shorter time to key milestones (i.e.; IND/CTA, FIH, PoC or NDA) using a programmatic drug development model are twofold:

- Maximized asset value
- Enhanced corporate-level financial performance (i.e.; reduced burn rate and extended runway)

Evaluating asset-level value for a programmatic versus transactional development approach begins with an assessment of commercial potential. This could be NPV of your asset at IND approval or at PoC, or market-based revenue assumptions. Corporate-level assumptions can also be assessed to understand the impact specific to your company's operations and financial performance.

A programmatic model has the potential to save an estimated 1 to 1.5 years from lead candidate selection through to PoC.

"When we look at a deal, we are considering the value of the asset not just the revenue forecast. If a biotech company we were considering as a partner were to walk in with a comprehensive economic assessment that included direct and indirect cost analysis, as well as the traditional financials, I'd certainly take a more serious look. If you can show me how you are working to increase the value of your molecule, that's interesting."[8]

Specific metrics can be modeled to evaluate the relative value offered by each approach. It is important to include the following in your assessment:

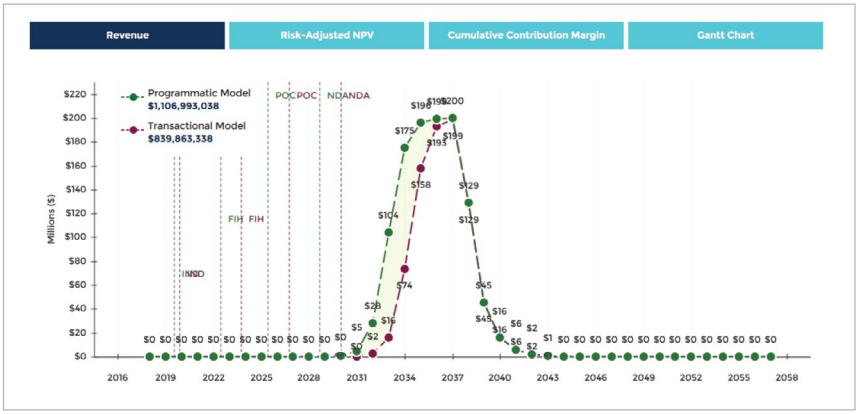
- **Asset-level value metrics:** Financing metrics that quantify the revenue and asset value.
  - Cumulative product revenue
  - Present value (PV) of cash flows
  - NPV of contribution margin
  - Risk-adjusted NPV (rNPV)
  - Break-even analysis
- **Corporate-level metrics:** Analysis of the relative value offered by each approach and the impact on corporate financial performance metrics.
  - Burn rate
  - Available cash
  - Runway

Based on the side-by-side comparison in our small molecule critical-path development scenario, following a programmatic model, while maintaining a similar burn rate, decreases the period of spend and increases the corporate runway. According to one executive-level drug developer, "[a]vailable cash and runway are important metrics to me. They tell me how efficiently I'm using our resources. The longer I can extend my runway the greater the time I have to build value and ink a deal."[8]

Consider your asset and corporate-level inputs specific to your molecule/company

Asset	
Peak annual sales of asset	$200,000,000
Year of start of service	2018
Year of loss of exclusivity	2038
Years to peak sales from launch	6
Share loss post loss of exclusivity	65%
Cost of capital	18%

Asset value increases demonstrably with a programmatic vs. transactional model



The programmatic model conserves available cash and sustains corporate runway

Runway at Completion of Program

	Transactional Model		Programmatic Model		Savings
Cash Available at End of Program	$24,406,227	-	$28,028,566	=	$3,622,339
Runway at Completion of Program (Years)	$20.1	-	$26.9	=	$6.8

Burn Rate

	Transactional Model		Programmatic Model		Savings
Annual Burn Rate (w/Overhead)	$1,215,099	-	$1,040,994	=	$174,105

Conclusion

Building value is the primary goal of today's biotech company CEO. Through considered economic analysis, the benefits of a programmatic model compared to a transactional approach are clear. Programmatic drug development offers flexibility, quantifiable cost savings (both direct and indirect) and, most importantly, time savings—all of which can build greater tangible value, and more quickly, for your asset.

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