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

Peter Sausen, PhD
Vice President, Strategic Development Solutions, Labcorp Drug Development

Bill Hanlon, PhD
President, Clinical Therapeutic Regulatory Sciences, Labcorp Drug Development

labcorp
Drug Development

Executive Summary

Minimizing development time is challenging yet critical to maximizing asset value. The faster you develop your molecule, the better positioned you are to realize the full value of your asset with longer market exclusivity for you or your co-development partner. How to accomplish this most effectively may surprise you. The answer lies in adopting the right drug development model. Through considered economic analysis, the value of a programmatic model over a transactional approach is made tangible, revealing the saving power, which can result in millions of dollars, that impacts both your asset and company financial performance.

Introduction

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

In an attempt to capture more value, a significant proportion of early drug development work has migrated from large pharmaceutical to smaller biotech organizations in the last 10 to 15 years. Because the cost of drug development continues to increase ($2.6 billion)[1] without substantial gains in number of products approved or time to market, many large pharmaceutical companies are focusing in-house resources on later stage development and commercialization. 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 (facilities and staffing), smaller companies are outsourcing drug development work to various contract research organizations (CROs), leveraging their expertise and resources.[4, 5, 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 fully enable the greater opportunity to 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 CRO prospectively plans, and then optimally performs, a set of pre-defined 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 more expeditiously. The early adopters of the programmatic model **have realized up to 30% improvement in time savings on their program.**[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.

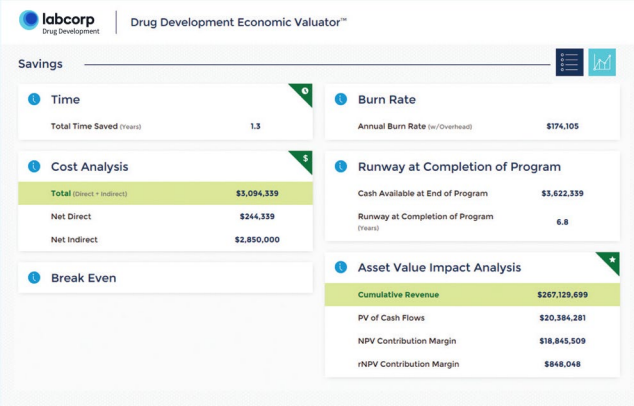
For example, by successfully adhering to promised timeline commitments and milestones, smaller organizations may gain access to additional rounds of funding.

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 new drug application (NDA).

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

When evaluating an outsourcing partner, finding one that has expertise spanning preclinical development through clinical post-approval services can offer valuable efficiency and insights for your program. Explore how your CRO partner can help you with the following services:

Preclinical Development Services

- Lead optimization
- Nonclinical safety assessment
- Non clinical drug metabolism and bioanalytical services

Regulatory Affairs

- Agency meetings
- Regulatory dossiers preparation and submission
- Strateg

Clinical Development Services

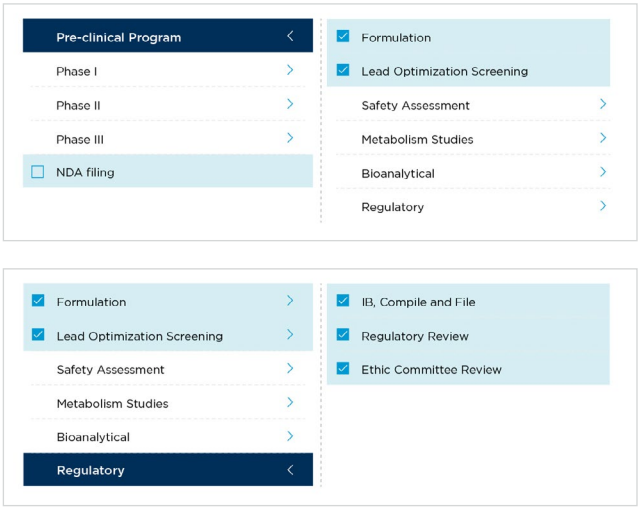
- Phase I
- Phase II
- Phase III
- Central laboratory and bioanalytical
- Biomarker development
- Companion diagnostics

Post-Approval Services

- Pharmacovigilance
- Phase IV studies
- Line extensions

> "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]

Understanding your strategic and program goals up front helps you to prospectively plan your scope of work



This breadth of experience can 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. Decreasing the number of partners can improve efficiency, communication, vendor management time and ultimately reduce time lag between studies.

Cost

Drug developers often expect that a transactional, multiple-vendor based 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."[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 start-up time, and the potential to reduce the need to add internal support and 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 both of 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 vs transactional approach to drug development

It has been found that between 2 and 10 internal headcounts[1] or full-time equivalents (FTE) 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.

Indirect Variable Cost	
Cost/FTE	$225,000
FTE Reduction Ratio with Programmatic Model	50%

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

Minimizing development time is challenging, yet critical to 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]

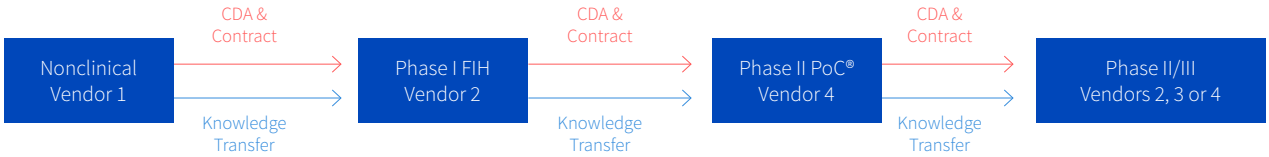
A programmatic model improves communication between expert groups, adds insight and preserves program and molecule knowledge, all of which saves time versus a transactional or multiple-vendor approach.

- **Improved Communication:** Consider the time it takes for internal communication between 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.

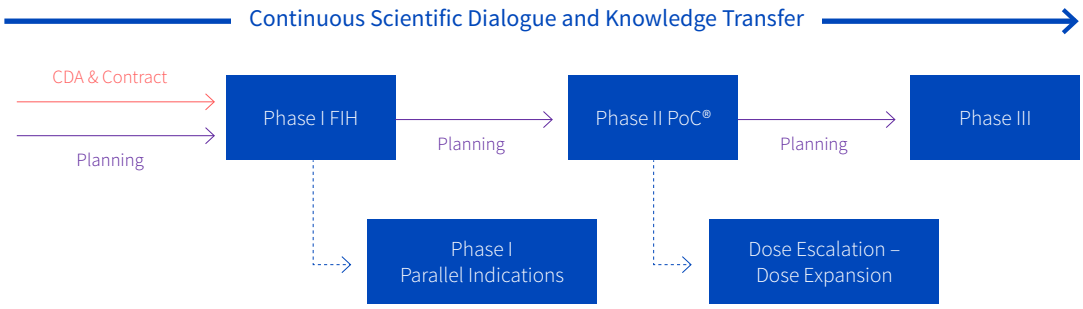
> "How much time did we "lose" in the development of our molecule? I'd say almost 2 years over the course of the program."[8]

Improved communication and planning yields greater foresight.

Multi-Vendor, Transactional Outsourcing



Programmatic Outsourcing



- **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 proof of concept (PoC®).

Value

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

- 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, multi-vendor 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:

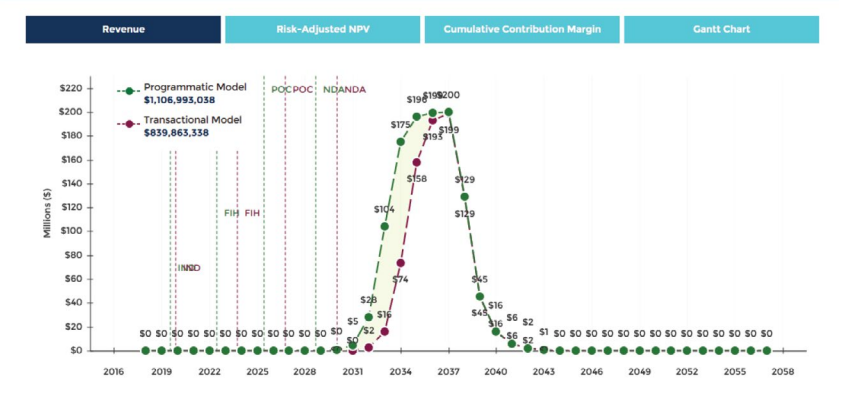
- **Asset-Level Value Metrics:** Financing metrics that quantify the revenue and asset value.
  - Cumulative product revenue
  - Present value (PV) of cash flows
  - NPV of contribution margin
  - Risk-adjusted NPV (rNPV)
  - Break even analysis
- **Corporate-Level Metrics:** Analysis of the relative 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, "Available 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

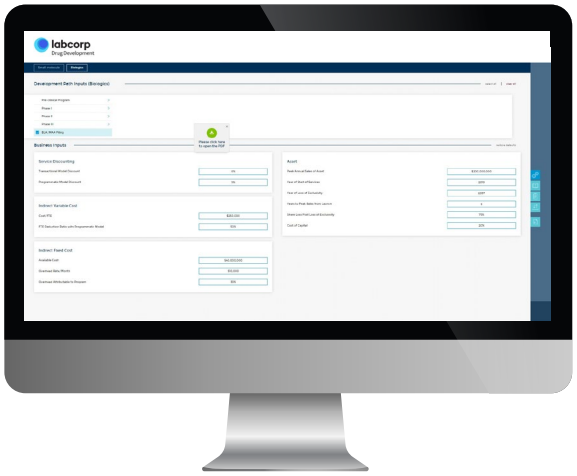
Conclusion

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, more quickly for your asset.

Make an Easy Economic Assessment of Your Program

To understand the value that a programmatic approach to drug development can provide for your program, one of our drug development directors can meet with you to compare the economic value of a programmatic versus transactional approach using our **Drug Development Economic Valuator™**. This unique tool easily enables you to evaluate direct costs (i.e., costs paid outright for services) as well as indirect costs (i.e., internal FTEs) needed to support your development program. Using a drug development critical-path analysis approach, time savings and the economic value of time on your asset can be compared, as well as the impact on corporate-level financial performance metrics – such as burn-rate, NPV of your asset, optimal timing to license or exit, and other key decision metrics.

You'll find flexible, comprehensive and integrated drug development solutions that can save you time and maximize your asset value. To learn more about our programmatic model and Drug Development Economic Valuator™, contact your business development representative.



In Pursuit of Answers™

Work with the world's most comprehensive drug development company. We're dedicated to advancing healthcare by providing high-quality nonclinical, clinical and commercialization services to pharmaceutical and biotechnology companies to help reduce the time and costs associated with drug development. With broad experience and specialized expertise, we're in a unique position to supply insights that go above and beyond testing. We have helped pharmaceutical and biotech companies develop each of the top 50 prescription drugs in the marketplace today.

We also offer laboratory testing services to the chemical, agrochemical and food industries and are a market leader in toxicology services, central laboratory services, discovery services and a top global provider of Phase III clinical trial management services.

Together with our clients, we create solutions that transform potential into reality.

labcorp
Drug Development

References
1. DiMasi, Tufts Center for the Study of Drug Development, March 2016. http://csdd.tufts.edu/news/complete_story/tufts_ csdd_rd_cost_study_now_published
2. Are M&A Replacing R&D In Pharma? Forbes, April 2015. https://www.forbes.com/sites/nicolefisher/2015/04/22/are-ma-re-placing-rd-in-pharma/#7112101ea21d
3. Experts advise Big Pharma to Shift to In-Licensing, *FierceBiotech*, February, 2010. http://www.fiercebiotech.com/biotech/experts-advise-big-pharma-to-shift-to-licensing
4. How can pharmaceutical and life sciences companies strategically engage global outsourcing? Price-Waterhouse Coopers, 2015. https://www.pwc.com/gx/en/pharma-life-sciences/pdf/pwc-pharma-outsourcing.pdf
5. Getz, Wenger. High Times for the CRO Heavyweights. *Scrip Supplements*, March 2007. http://csdd.tufts.edu/_documents/www/2708Getz.pdf
6. Getz, Lamberti, Mathias. Resizing the Global Contract R&D Services Market. *Contract Pharma*. May 2012. http://www.con-tractpharma.com/issues/2012-06/view_features/resizing-the-global-contract-rd-services-market/
7. Labcorp Drug Development, Inc. Assumptions and calculations of transactional vs. programmatic outsourcing models, based on real world experience supporting drug development programs for more than 1,500 biotech clients each year, more than 300 IND/CTA-enabling programs and more than 100 FIH trials executed in past 5 years, as well as experience leading Early Phase Development Solutions programs, global clinical trials, regulatory submissions and market access research and commercial stakeholder insight.
8. Primary Market Research: "The Economic and Value Drivers of Drug Development Impacting the Cost and Time Factors of a Program," April 2017, third-party research study sponsored by Covance, Inc. Based on Covance Economic Valuator simulation of small molecule, critical-path analysis. Covance, Inc.

Learn more at drugdevelopment.labcorp.com

labcorp Drug Development