



Tufts Center for the Study of Drug Development

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Cross-functional team focus on marketing is key to project success

Industry says speed-within-market is as important as speed-to-market

- Average annual new drug approvals in the U.S. doubled from the 1970s to the 1990s while R&D costs more than quintupled.
- Forecasting scientific needs provides a tool for managing the gap between potential projects and available resources.
- Development projects should aim for full commercialization of a new product, not just regulatory filing.
- Marketing and sales activity ideally should start 2-3 years before product launch.
- Information technology, yet to be fully deployed in servicing existing and emerging markets, will be decisive in integrating R&D with commercial activity.
- Cross-functional teams focused on patient markets enable portfolio management for a single compound.

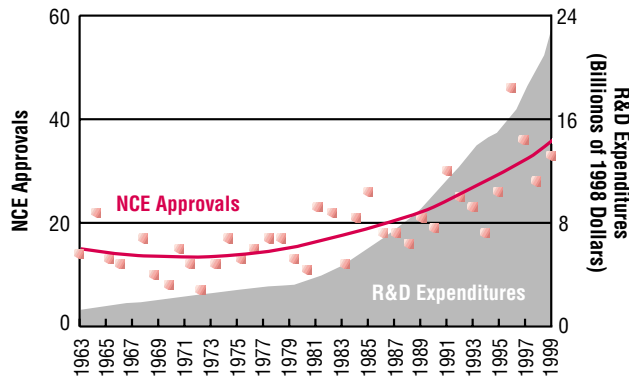
In the past, the research-based pharmaceutical industry tended to operate on the tenet that getting good products to market first was the surest path to commercial success. Today, much more is required. Fragmenting markets, strategic alliances, mergers, political change, price restrictions, and growing generic competition have radically altered the global market for pharmaceuticals. Speed to market is no longer sufficient. Speed within market is increasingly a critical success factor.

To better understand how to shorten development cycles and improve integration of commercialization and development activities, the Tufts Center for the Study of Drug Development recently convened a group of senior pharmaceutical and biotech executives. They exchanged experiences and insights, and shared ideas on what works and what doesn't. This *Impact Report* summarizes key points presented at this one-day R&D management workshop.

Join us at our next R&D management workshop — Nov. 8, 2001, in Philadelphia.

Rising R&D costs make the case for linking commercialization and product development

U.S. Drug Industry R&D Expenditures and NCE Approvals: 1963 - 1999



Source: Tufts Center for the Study of Drug Development, PhRMA

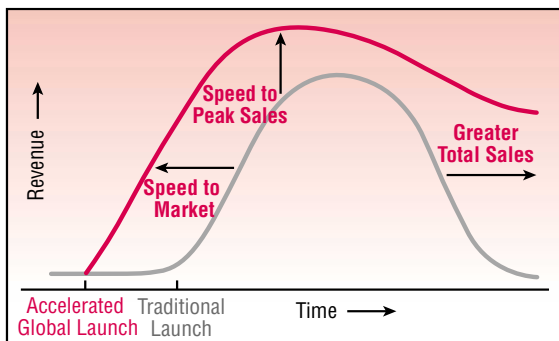
- NCE approvals in the U.S. are not keeping pace with R&D costs: average annual NCE approvals for the industry doubled from the 1970s to the 1990s while R&D costs more than quintupled.
- During the same period, the time to develop a new drug in the U.S., from preclinical testing to approval, stretched from 11.0 to 12.9 years.
- Lengthening clinical phase times have recently dropped, averaging 4.8 years in 1998-1999.
- Proven tools for speeding drug development include use of surrogate markers and endpoints, post approval research commitments, FDA/sponsor meetings, and rolling reviews.

Putting forecasting systems in place force the right internal discussions

- Systematic forecasting of scientific talent provides a way to manage the gap between projects that could be undertaken and available resources.
 - Decide what should be done in-house and what should be outsourced.
 - Plan at the full-time equivalent employee level; more granular detail doesn't gain much.
 - Work closely with the human resources department to recruit the right skill sets.
- Keep forecasting systems simple:
 - A spreadsheet model with 10 key variables will often be sufficient.
 - Each therapeutic area has its own assumptions and should have its own forecasting model.
 - Validate projections against actual resources consumed.
 - Strategic centralization of the system ensures consistency and a cross-functional view.
- The benefits of such systems accrue across the company by:
 - Forcing a portfolio management discussion: different views may exist, but they can't be ignored.
 - Helping project leaders identify resource sensitivities in their project plans.
 - Providing a coherent and consistent way to evaluate licensing opportunities.

Speed to market and speed within market together help improve lifetime product sales

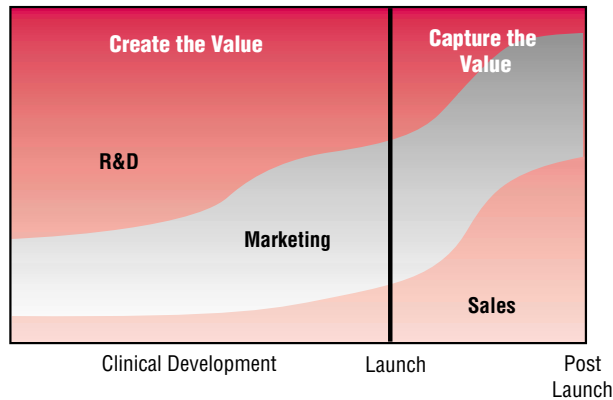
Shared Accountability Maximizes Product Opportunities



- The project goal should not only be regulatory filing, but full commercialization of a new product.
- Global commercial teams that begin life cycle management early on— before Phase III clinical studies begin — help achieve speed to peak sales.
- If life cycle management is not done well, sales will migrate to the lower curve on graph at left.
- Greater total product sales occur when actual end-users receive greater benefits from the drug.

Cross-functional teams eliminate silo thinking, maximizing accountability and product success

Customer Focused Product Flow



- Cross-functional teams exist throughout product life — R&D, marketing, and sales work together from development through post-launch:
 - Marketing and sales activity should start 2-3 years before product launch.
 - Post-launch R&D involvement leads to greater total product sales sooner rather than later.
- The goal of joint development and marketing and sales teams is to maximize resource use.
- Team members are best engaged when they share ownership of the entire product lifecycle; management's role is to ensure that sense of ownership.

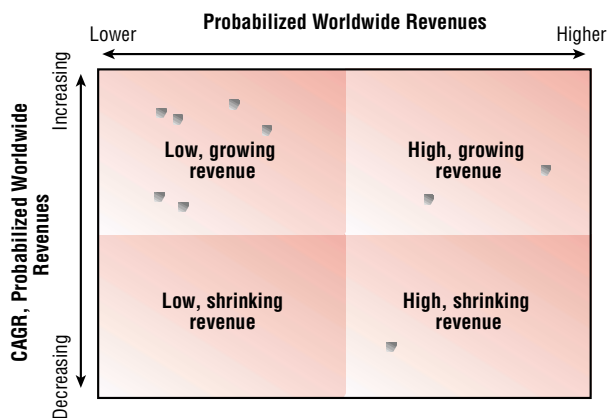
Competitive advantage flows from knowledge management within and between projects

Project Management Is Changing	
Traditional Focus	Customer-Market Focus
<ul style="list-style-type: none"> • Company standards • Deliverables • Overall project timing • Scientific detailing of package • Risk and contingency planning 	<ul style="list-style-type: none"> • Industry/customer standards • Strategy • Budget and cost forecasting • People and resource allocation • Outsourcing strategies and practices

- Knowledge management, largely unused in the non-scientific aspects of product management to date, should be rapidly deployed.
- Knowledge management provides the communication/market research infrastructure critical to the success of cross-functional teams:
 - Since blockbusters are rare and largely unpredictable, niche products will be the path to fuller commercial success. Knowledge management will play a critical role in understanding trends and servicing customers.
 - With key constituencies — physicians, end users, regulators — in constant flux, their demands and needs will require close attention.

Trade-offs across a range of launched and pre-launch products must be evaluated

Launched Products Compete for Resources Based on Near-Term Revenues and Growth



- Strategic considerations include:
 - Financial viability: Do the ends justify the means?
 - Franchise strategy: Does this fit with our business?
 - Risk analysis: Is commercial success likely
- Key success factors include:
 - Target patient population — indication selection speed vs. population vs. price
 - Medical education; patient awareness/compliance
 - Health economics — Endpoints relevant to payers
 - Capacity planning
- Other evaluation criteria include the ability to develop a portfolio for a single compound, the potential to leverage newly acquired expertise, and the long-term market value of a disease area.

Workshop Presenters

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About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development, affiliated with Tufts University, provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. The Tufts Center conducts a wide range of in-depth analyses on pharmaceutical issues and, in addition, hosts symposia, workshops, and public forums on related topics throughout the year.

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