

# The New Role of R&D

Why and how does it need to change?



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## Introduction

When you think about R&D in the Life Sciences industry, what comes to mind? Perhaps drug development, technology discoveries, lists of patents, or scientists in labs developing all kinds of new products. What you may not think about is how R&D can become the innovative heart of an entire organization to ensure the right drugs, devices and/or biologics get to market and make the impact. The goal of this paper is to provide an overview of why and how R&D needs to move from its current role focused mainly on development to a more central position at the core of all innovation and collaboration to ensure comparative effectiveness. It also will discuss the great opportunities and challenges that are involved in such a transformation.

## The New Business Environment

The recent economic crisis has caused many organizations to reevaluate and reinvent their business strategies to set a sustainable course for future growth. The most recent annual global CEO survey by PricewaterhouseCoopers concluded that global leaders were forced to make significant changes within their organizations, such as reducing headcount, selling off assets and preserving funds. Many business leaders also felt obligated to assess their risks and examine alternative plans they could execute.

The Life Sciences industry, which includes pharmaceuticals, biopharmaceuticals, medical devices and biotechnology, in particular face unique challenges. Key challenges include:

- Shift to Solutions: shifting from a product mindset to a solutions mindset given the rise of personalized medicine
- Revenue “Replacement”: bridging the gap between the \$100 billion in sales from medicines over the next five years as intellectual property protections expire and the collective value of products/solutions in the pipeline that could be launched, which total \$30 billion. Major Life Sciences companies, such as Johnson & Johnson, are projected to have up to 50% of sales at risk due to generic erosion over the next five years<sup>[c]</sup>
- Differentiation: ensuring products / solutions are better than others on the market given increased customer, payer and FDA scrutiny (comparative effectiveness). If the product / solution does get on the market, providing differentiated products / solutions to secure future healthcare funding. Finally, identifying how to compete with the increased competition from generics,<sup>[b]</sup> given patent expirations
- Efficiency and Effectiveness in Product Development: addressing the unrelenting slippage in product development while, at the same time, managing increased complexity given new protocol requirements, global trials, etc.
- Change Management: managing the torrent of change coming from M&A; significant cost and workforce reductions; new/shifting R&D processes using new technology (e.g., EDC) and methods (e.g., Adaptive). Introducing even more change, the industry as a whole is currently making fundamental changes to its operating structure

Life Sciences CEOs realize a new model is required to drive sustainable growth; as a result, these CEOs are planning to make radical changes to their companies in the coming years, and a majority of them are planning transformations to achieve long-term profitable growth. Over the next three years, an astounding 98% of Life Sciences CEOs surveyed indicated they are confident their companies will grow revenues, though a full 40% believe recovery won't set in until 2011. As a customer driven market seems to be driving the market more and more, 73% of CEOs believe consumers will play a more active role in the development of new products and services. In addition, recruiting and retaining highly qualified researchers is essential for Life Sciences companies to maintain effectiveness, as they depend on innovation to drive growth.<sup>[a]</sup> While confidence may be rising, challenges still remain, and innovation is needed. CEOs will be pulling several key levers of innovation to drive sustainable growth:

Innovation Lever	Definition	Example
<b>Business Model Innovation</b>	Innovation in the way companies generate revenue, including which customers are served; what value proposition is offered; and what channels are used to reach customers. The value proposition needs to be higher – comparative effectiveness is a vital factor and the result is step-change increments in growth	Companies like Novartis are now starting to recruit patients by going directly to consumers via social media
<b>Operational Model Innovation</b>	Innovation that improves the effectiveness and efficiency of core processes, methods, techniques, technology designs as well as organizational models and functions to achieve competitive differentiation and positive disruptions resulting in new market opportunity	Trial designs using adaptive trials; the application/institutionalization of Kaizens; technology using an eClinical platform, such as EDC, IVRS, CTMS; business intelligence platforms integrating data across all clinical trials; EAI, ETL based data harmonization; shift toward e-submission and an extreme focus on leadership nurturing and cultivation (e.g., AstraZeneca)
<b>Collaborative/Open Innovation</b>	Innovation that shares expertise, costs and benefits; continuous <u>two-way</u> engagement/exchange with internal and <u>external parties</u> to bring <u>insights</u> and <u>economic impact</u>	GSK and Pfizer spun off parts of their organization into a joint venture to boost the efforts of HIV drug development. The new venture is called: ViiV Healthcare
<b>Scientific Innovation including Products/Services/ Solutions Innovation</b>	Innovation that results in new discoveries that are successfully commercialized; established products/services/solutions that are “upgraded” and/or reformulated . Innovation here results in products/services/ solutions that stand out and change the industry landscape	Science innovation that drives new products/services/solutions. Example: product differentiation and variation addressed in protocol development (e.g., Vion’s special protocol assessment for Onrigin Injection). Other examples include solutions such as personalized medicine
<b>Market/Customer Innovation</b>	Innovation that is driven by latent customer wants and needs; proactively shaping demand and creating “net new” markets. Typically this involves Identification of market headroom (either new market segments or discontinuities in existing market spaces) to create opportunities to expand into white-space	Life Sciences companies are shifting from “marketing” to customers to interfacing directly with patients to let them know the value proposition of their products/solutions. Marketing efforts are starting to focus on microsegments. Coupons are being provided to drive demand (e.g., Advair)

While taking into account all levers that can formulate an innovation blueprint, how can companies achieve a balanced view of the levers to achieve sustainable growth? AC believes that R&D can and should be at the center of innovation and that R&D is a key enabler of all types of innovation.

## Current State of R&D: Key Challenges

Results are getting worse for Life Sciences R&D. Failure rates of experimental drugs are on the rise: the number of products abandoned in late-stage Phase 3 trials has doubled to almost 40 in 2007-2009, compared with 2004-2006; this is a 50% increase.<sup>[f]</sup> Also, now it takes 12-13 drugs to enter the pre-clinical phase to gain one commercial success vs. 8 in the year 2000.<sup>[g]</sup> Direct and indirect costs to get one commercial success have nearly tripled, going from \$800 million in the year 2000 to \$2.5 billion in the year 2010. Meanwhile, R&D cost growth has outpaced sales and gross margin growth rates significantly. One report from the U.S. Census Bureau demonstrates a disparity of growth rates over several decades: the growth rate of deflated gross margins was shown to be 4.23% per year, compared to the 7.51% growth rate found for R&D outlays. In fact, the growth rate of R&D outlays has outpaced the growth rates of gross margins since 1996.<sup>[i]</sup> The study also states that if R&D was covered exclusively by domestic gross margins, the continuation of growth trends experienced since 1962 would indicate that R&D outlays would exceed gross margins in the year 2025. And while profits from overseas sales help repay R&D costs, the U.S. is still the largest single market for U.S. drug companies' products, which makes the slowing of R&D growth rates likely in the long run.<sup>[h]</sup> In addition, only one in five marketed drugs recoup R&D costs. New products developed over the last five years account for a total of 7% of current revenue.

In addition to the disappointing results and financial dynamics outlined above, R&D operational performance is also poor. Greater than 90% of all clinical trials are delayed due to over-ambitious timelines and difficulty with patient enrollment. One-third (35%) of trials are substantially delayed due to 'Rescue Mode' patient recruitment activities. Eighty percent of studies run over by 30-42%, or an average of 6 months.

What are Life Sciences companies doing to address this? They are cutting people and costs. In the first three months of 2010, the industry cut 25,857 jobs.<sup>[j]</sup> Life Sciences companies have also cut back on R&D activities in 2010 to preserve funds. Aggregate spending on developing new drugs fell by 0.3 percent. Cumulative investment as a proportion of sales decreased to 15 percent across the Life Sciences industry.

Unfortunately, these effectiveness and efficiency challenges have all led to the same result: failure rates are staggering. An incredible 65% of product launches fail, and 46% of product development resources are spent on products that fail or never make it to market.

These results combined with the aforementioned opportunities and challenges clearly show one thing: an R&D transformation is needed. R&D needs to work on the right products / solutions that will bring the most value and do more with less!

## What Needs to Change? A New Role for R&D

R&D transformations have been shown to improve net profit and drive revenue by focusing on the right products/solutions with the right processes, people and technology. They can reduce operational costs associated with product/solution development while enhancing financial performance. The key is to have a broader and more consistent injection of innovation into development life cycle.

To achieve this, Life Sciences companies will need to make some significant shifts. The heart of the shifts lies in looking at a new product/solution to determine "feasibility" to ensuring innovation, optimization and viability at every step of discovery and product/solution development. **Rigor** is critical in this new approach and R&D needs to be at the heart of driving the change. Below we have outlined the new role of R&D:

- **Innovation and Ideation:** R&D must become the innovation steward, focusing not just on products and solutions innovation, but also operations, business model, culture, policy & society, market/customer as well as collaborative/open innovation. R&D also must manage ideas in the pipeline to ensure resources are focused on the ones that will reap the most rewards. Managing ideation will ensure that all good ideas are not only heard, but also properly addressed and brought to fruition. R&D parameters include: the probability of successful transition from one stage of product/solution discovery and development to the next, the phase cost for each project, the cycle time required to progress through each stage of development the cost of capital and, finally, the estimated net profit from the product/solution
- **Collaboration:** R&D must create a collaboration hub to take advantage of the best ideas, both internal and external. Effective collaboration shortens the product/solution development cycle by providing support solutions and processes while aligning market insight, research delivery and product development. R&D should view collaboration not just as a way to ensure materials go where they should, but more as an opportunity to gather insightful ideas from all internal and external areas of the organization to deliver the best products/services/solutions at the right time
- **R&D Strategy:** R&D must develop a strategy that considers customer demand, market performance and core business strategy alignment. No longer can R&D strategy just focus on internal R&D issues—it must go beyond processes and logistics and focus more on the business as a whole. R&D strategy must transform itself to not only align with but also help shape and drive the overall business strategy. In addition, R&D needs to assess product/solution development at every stage and move from looking just at feasibility but optimization and viability – from a medical/scientific, operational as well as comparative effectiveness standpoint. The strategy should include ensuring there is a rigorous approach to end-to-end product/solution development
- **Success Measurement:** R&D must develop a metrics approach that ties R&D investment to business performance. Measuring the wrong things can be just as bad as measuring nothing at all, leading to resource inefficiencies and product/solution launch failures. By zoning in on a set of solid metrics, companies can ensure their money is going toward the R&D investments that will bring the greatest impact
- **Leadership:** R&D must create an organized leadership structure with clear goals and strategies, along with assigned accountability. Without leadership, an R&D process is just that – a process. It takes an organized leadership structure to turn a set of R&D processes into an effective R&D unit that runs efficiently while staying aligned with the overall company strategy. Further, leadership commitment is necessary to identify long-term objectives, challenge the organization to do more, create the right environment, dedicate resources and share the risk, get the right people with the right skills, and approve or kill ideas to accelerate product/solution cycle time

Tackling these five key changes will allow R&D to become what it needs to be: The Innovation Steward, The Collaboration Hub, and One of the Key Business Leaders.

## **T**ransforming R&D to Realize its Potential – An ILRDP Approach

AC has developed a comprehensive approach to transform Life Sciences R&D using AC's Industry Leading R&D Performance Framework (ILRDP). ILRDP shifts the paradigm in how R&D transformation can be performed for Life Sciences companies. ILRDP is a diagnostic tool for more than 100 functional components of R&D and contains key performance indicators and their associated benchmarks; proven leading practices within the Life Sciences industry as well as those from other industries as well as risks with associated risk mitigation approaches. All these elements add up to approximately 10,000 diagnostic assessment dimensions for not only operational improvement areas, but also those that enable innovation and effectiveness.

ILRDP transformation identifies how R&D can become more effective (focusing on the right products/solutions) and efficient (ensuring “how” R&D brings products/solutions to market is optimal). ILRDP also aligns companies’ R&D with their business strategies and identifies operational and maturity improvements. This framework encourages companies to develop a fresh perspective on the R&D business model and includes three key approaches: “insight development,” “tops down” as well as “bottoms up.” The ILRDP framework is used as the basis of analysis:

1. **Insight Development:** Develops insights across all categories of innovation and derive key growth and operational opportunities. Innovation insight analysis results in a combination of scientific, operational and comparative effectiveness findings that feed into the strategic imperatives for R&D and “Tops Down” analysis
2. **Tops Down – Strategic Intent and Scientific Viability:** Uses the business strategy and net new insights to identify strategic imperatives for the R&D unit; ensures the market (comparative effectiveness) and scientific viability of the current R&D and commercialized portfolio resulting in a proposed portfolio disposition; determines the capabilities that will enable imperatives and can support the new portfolio; and pinpoints people, process and technology requirements to support new R&D strategic imperatives and the new portfolio
3. **Bottoms Up – Operational Execution Focus:** Use detailed ILRDP-based benchmarking analyses, risk assessments, peer and ecosystem assessments as well as project retrospectives to identify operational gaps. The value of fixing those gaps is then calculated, and the people, process and technology requirements to fill those gaps are identified from an operational perspective. Define cost allocation for baseline and perform cost analysis for future state

Some highlights of our analysis approaches are outlined below:

- A few of the key analysis assessment dimensions include: Target Product Profile and Protocol, Patient Recruitment Strategy and Tactics, Patient Management, Logistics/Enrollment/Location, Operations, Business Management, Project Resources and Comparative Effectiveness Feasibility
- Project retrospectives study all three analysis dimensions above: strategic intent (the “what”), scientific viability (the “why”) and operational execution (the “how”)
  - Strategic intent includes, among other items: insight development, comparative effectiveness
  - Scientific viability, including, but not limited to: target product profile, protocol, endpoints, population, drop-out and enrollment rates, dose/route/BA and target label claims
  - Operational intent includes items such as: clinical operations/enrollment/investigators/sites, regulatory management, data management, biostatistics, drug supply, labs medical writing, medical/safety monitoring
- Each assessment framework has a specific analysis plan that indicates the strategic question, the data required, as well as the source of the data

The three work streams then come together in an integration phase, where all of the people, process and technology requirements are bundled into initiatives and prioritized through a robust set of filters. The final steps are then to create business cases/P&L impact models for the initiatives and a roadmap for the client to follow as it progresses through the R&D transformation.

Using this approach will enable companies to embrace the R&D opportunity and better prepare them for the future. It is AC’s belief that the ILRDP framework will push the business strategy to new horizons, identifying new realms for net profit growth. AC has a mission to help companies achieve such a level of R&D superiority, and it is prepared to combine its own excellence in research with proven methods to develop recommendations that improve costs, revenues and strategic differentiation in the Life Sciences industry.

## Net Profit Impact!

Optimizing R&D capabilities can bring great opportunities to companies when done correctly. In 2008, the largest 13 out of 15 Life Sciences companies with revenue greater than \$12 billion employed an average of 30% of total staff in R&D functions. Of these, the companies that invested more in R&D appeared to have more promising long-term growth potential.<sup>[e]</sup> The answer may be reallocating investments vs. reducing them.

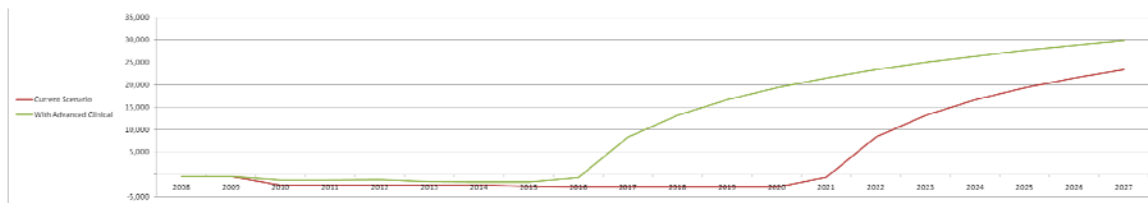
Based on AC experience, the impact of improving R&D's people, process and technology in a clinical trial is significant. This is confirmed by others in the industry.

### Impact of Improving the Resource Efficiency in the Clinical Trial Process

Improving non-core functions by creating a shared services delivery model staffed with subject matter experts can lead to 30-40% direct cost savings (e.g., labor associated with the functional tasks) and even larger indirect cost savings (e.g., improvement in quality to the point that secondary reviews are unnecessary and staff can be reassigned to other projects)



### Implication: Between \$600K and \$8MM per Day of Regained / Recaptured Revenue



Sources: Inc Research, 2009; Advanced Clinical Client Example, 2010

## Endnotes

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