

The Deloitte logo, consisting of the word "Deloitte" in a white, sans-serif font with a small yellow dot at the end of the word. The background is a solid blue gradient with a large, curved, reflective glass tube and a glass vial with a stopper, both containing clear liquid, positioned diagonally across the frame.

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Change and Disruption in the Pharmaceutical Industry

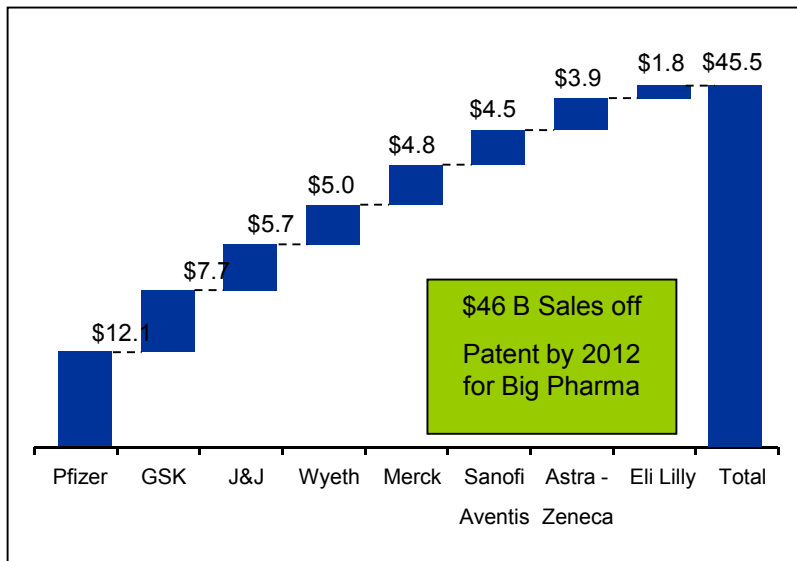
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Replacing aging portfolios is the core of large Bio-Pharma's growth challenges and can only be solved by assuming and managing unprecedented levels of scientific risk

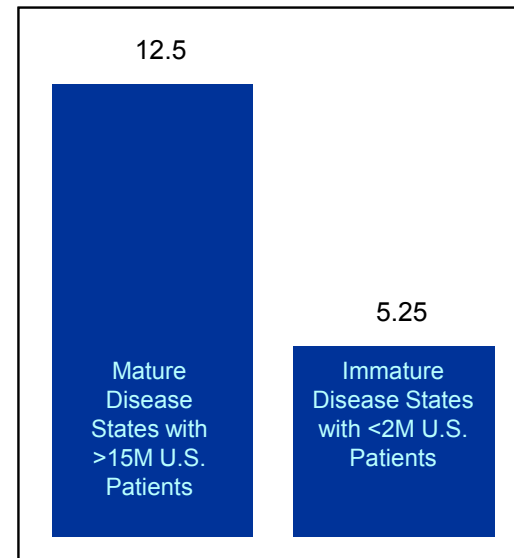
Product Sales at Risk from Generics

Sales of Key Products Off Patent by 2012 (\$billions)



Product Saturation in High Value Disease States

Average number of pharmaceutical company products in sample disease states



Sample Disease States

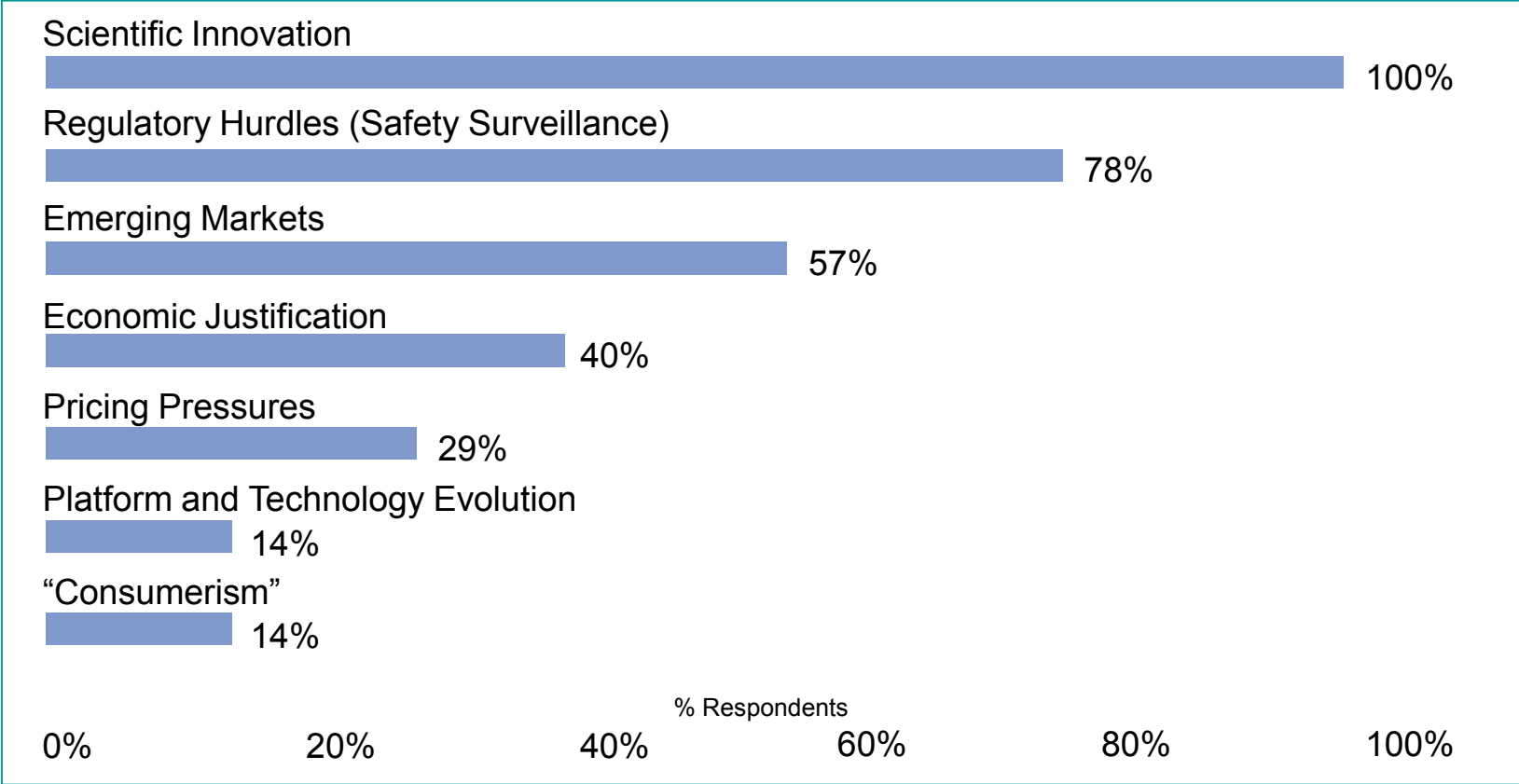
- Hypertension
- Hyperlipidemia
- Diabetes
- Depression
- Breast cancer
- HIV/AIDS
- Lupus
- Crohn's Disease

The ability to focus R&D efforts on new scientific frontiers will be essential to replenish diminishing pipelines and to expand product portfolios

Source: 2006 Company Annual Reports; WebMD list of treatments in 2005

Senior Bio-Pharma executives concur that scientific uncertainty will drive the most significant changes to business strategies and operating models

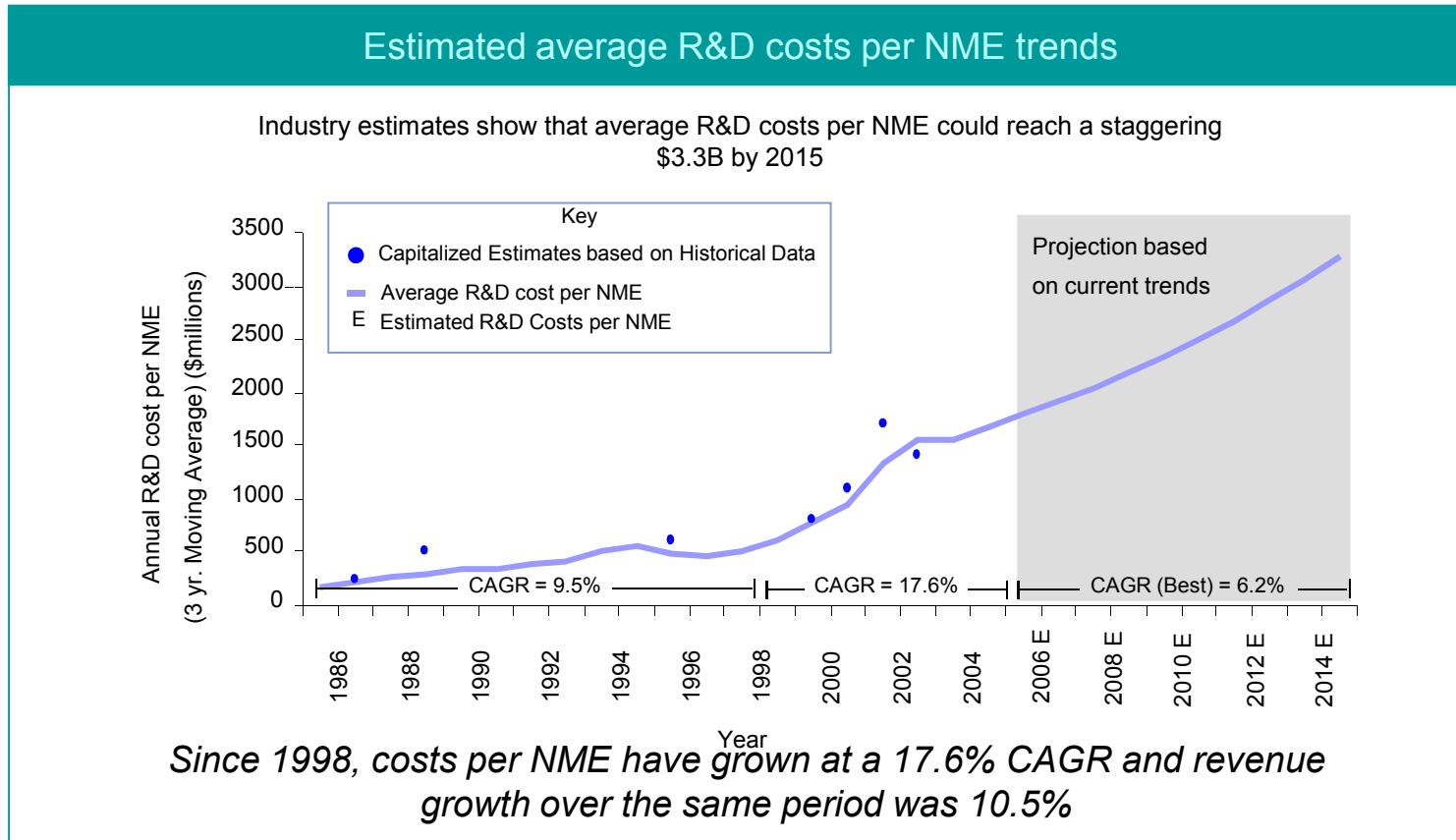
Which drivers of uncertainty will have the greatest impact on the R&D model in the next 5 years?



Industry executives expect the pursuit of novel scientific innovations to lead to expanding portfolio strategies

Source: Deloitte “Strategic Partnering in Life Sciences” – Customer Needs Interviews 2008

“More irons in the fire” is a logical hedge against future uncertainty, however the existing R&D operating paradigm will not scale to support expanding pipelines



Without a “game changing” approach to improving R&D productivity, Bio-Pharma cannot systematically assume the risk necessary to pursue true breakthrough innovation

Deloitte Analysis: Normalized Projections; NME cost estimates are plotted by year of currency quoted in the original report; From left to right, the blue circles represent estimates by Tufts, BCG, Lehman, Tufts, DOC, Bain and Wyeth; Graph Data Source: PAREXEL’s Bio/Pharmaceutical R&D Statistical Sourcebook 2006/2007

And while a new R&D approaches are being tried by Big Pharma, none have appeared to date to generate significant increases in R&D productivity

For example, some of the approaches to change R&D recently undertaken include;

Simplifying R&D

- **Roche's** restructured management process for managing its' new Disease Biology Area R&D organization

Decoupling R&D

- **Pfizer** recently decoupled its R&D - Tasking R with creating knowledge and understanding and D on efficient execution of focused development programs through targeted business units

Managing the R&D interface

- **GSK's** use of Centers of Excellence to efficiently manage the R&D interface for clarity and speed

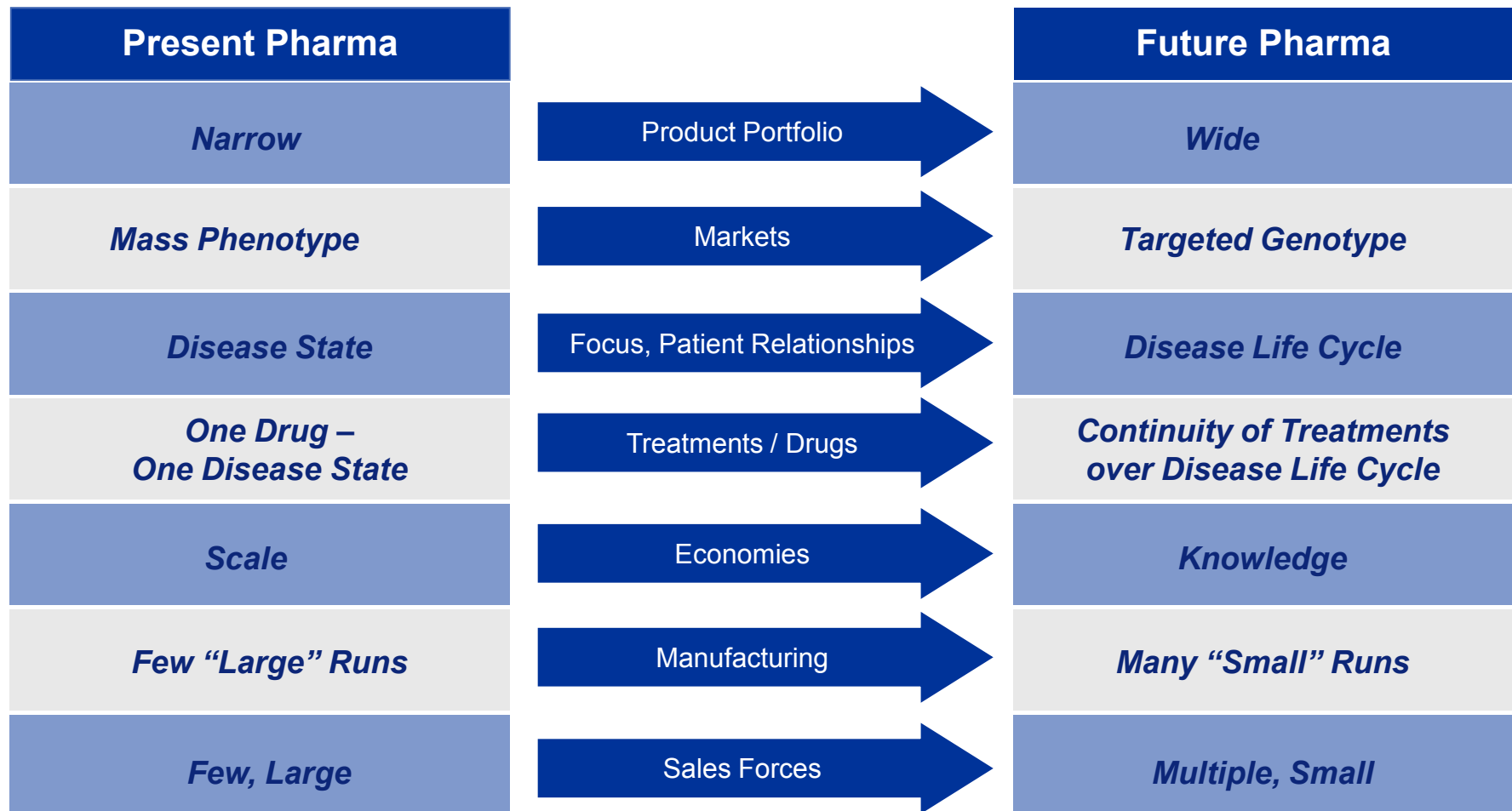
Accessing Global Knowledge to solve in-house R&D problems

- **Eli Lilly's** creation of its Innocentive subsidiary which is essentially a global exchange for problems and solutions

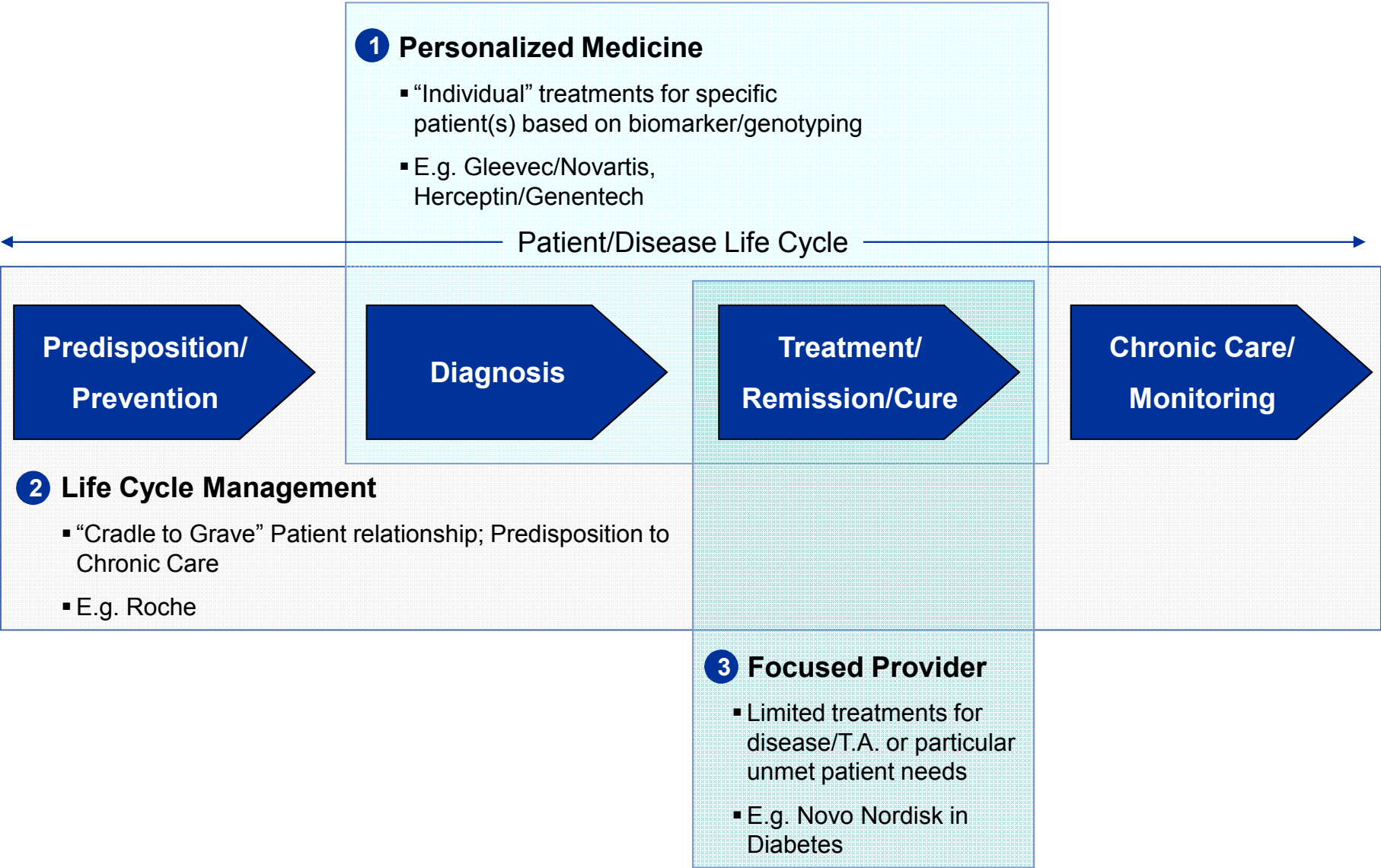
Virtual R&D Processes

- **TAP** and **King Pharmaceuticals** outsourcing of Research, in-licensing development candidates and concentrating on drug development, with the help of external suppliers e.g.. Clinical Research Organizations (CRO)

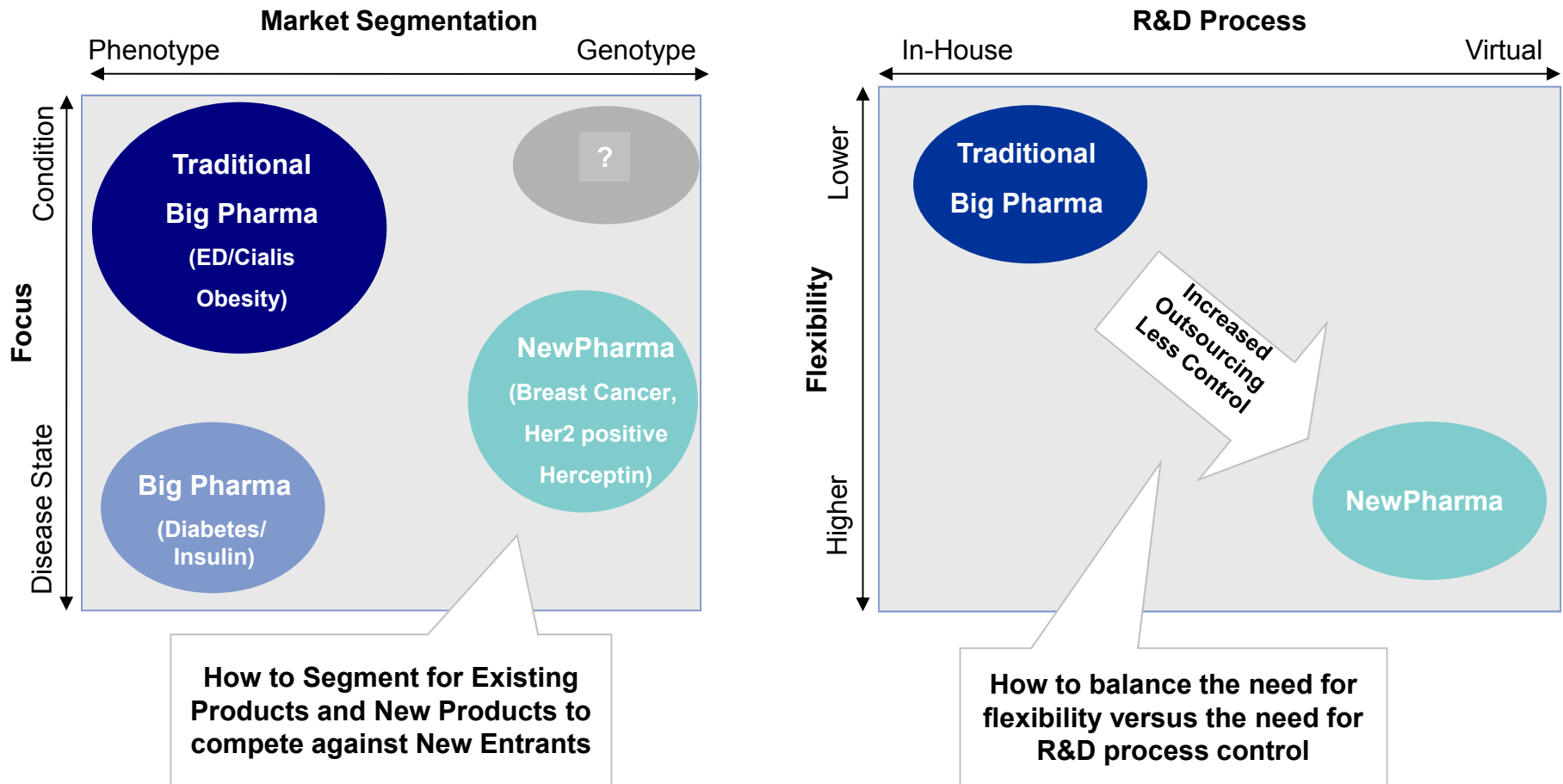
The industry's Emerging Landscape



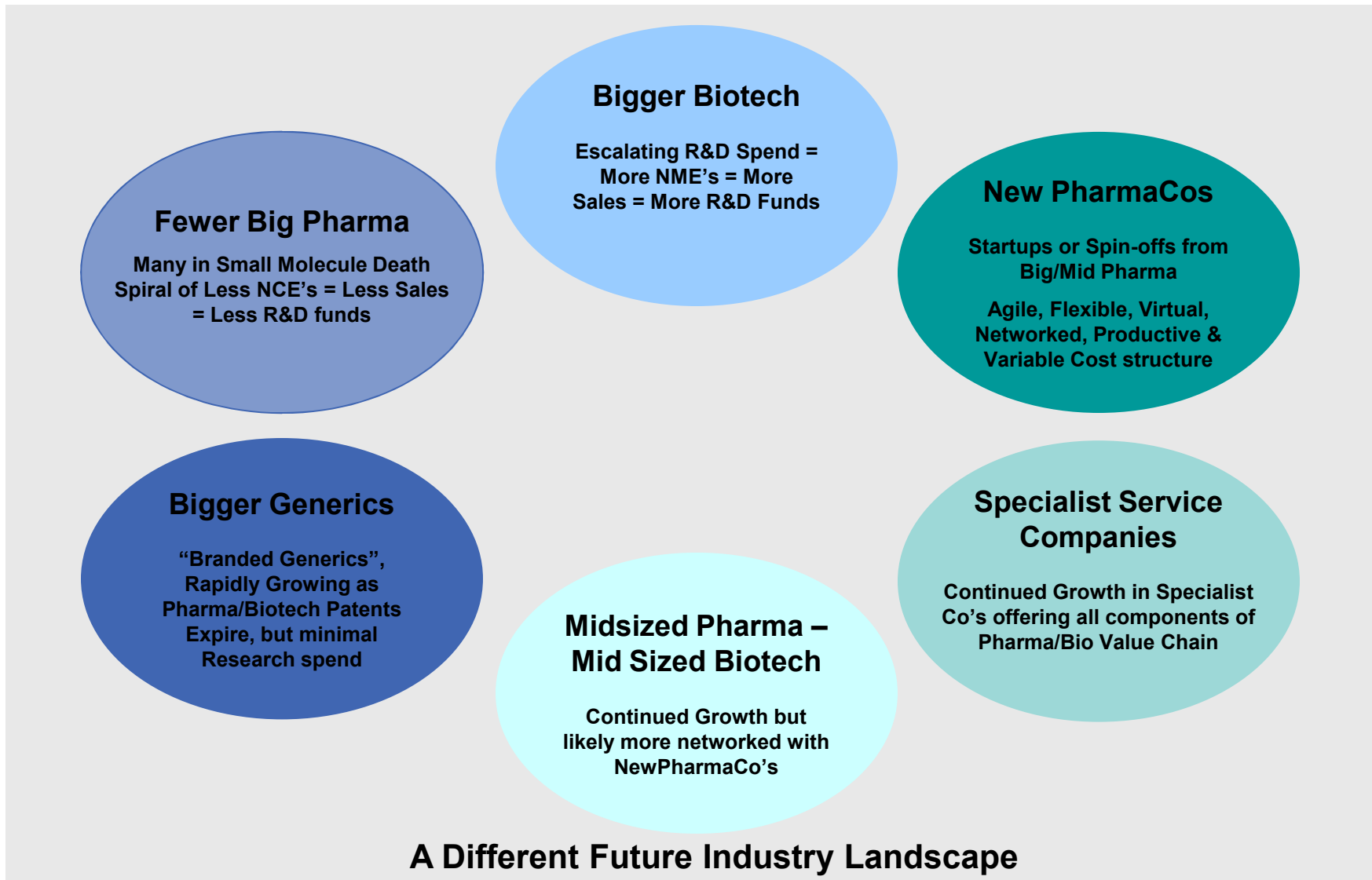
Within this landscape, Pharma, going forward, faces difficult choices about where to focus on the Patient/Disease life cycle



Pharma, further has to choose how to segment its market and structure its R&D process to deal with this changing environment



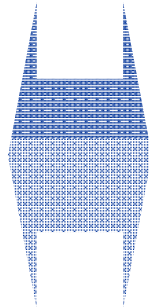
With this fragmentation, a different industry landscape is emerging



With flexibility and productivity declining, Big Pharma is increasingly vulnerable to New Entrants with new business models disrupting the status quo

Existing Big Pharma

- Large, global, complex
- Increasingly partnering with outside specialists – biotech, CRO's, CMO's – with mixed results
- Rigid, internal processes
- Still dominated by large market, oral products
- Slow decision making with numerous matrix overlays on the organization structure
- Some large scale economies, often offset by organization's complexity



Potential New Entrants

- Focused on niche market segments, with targeted treatments potentially new and alternate delivery mechanisms
- Patient specific segmentation based on genotype attributes
- Biomarkers versus clinical end points
- Potential for price premium based on higher efficacy for differentiated market segment
- Highly virtual organizations using extensive external collaboration and partnerships
- Flat organization structures with clear, rapid decision making and minimal dual reporting
- Scalable cost structures
- Explicitly deal with external uncertainty in organization structuring and strategy
- Different models possible based on value chain & life cycle positioning
- Common key characteristics – fast, agile, real patient/customer focus and relationship management via mass customization
- High innovation rates by employing latest best practices for product development

Big Pharma has the potential to be the primary source of these New Entrants if it is willing to change its existing business model

The changing Industry landscape will shape the future R&D Organization

Key Change Driver

- Market Segmentation via Genotyping/Biomarkers
- Expanding Knowledge Base in Genetics and Large Molecule Technology
- Accelerating Technology Change and Increased Specialization
- Unbundling Diseases into multiple related conditions/states
- Many Technology Platforms emerging in large molecule; Dominant technology platform or conceptual framework unlikely

Implications for R&D

- R&D structured to support a “Disease”, rather than a “Drug”, strategy
- Disease specific R&D units with rich information/concept transfer across the different units to identify/exploit common mechanisms
- R&D targeted to create Patient/Disease Franchises, with multiple treatments over disease life cycle
- Genotyped patient selection and biomarkers rather than phenotype and clinical end points
- Partnering/In licensing to complete treatment portfolio for Franchise
- Multiple Knowledge Bases required to cover both Small and Large Molecule Science, Infectious Agents, Vaccines and Platform Technologies
- Virtual Networks and Collaborative Communities needed to ensure R&D flexibility, access to knowledge on technology platforms and concepts

But current “hot” issues and organizational constraints are going to slow Big Pharma’s transition to this future organization

Current “Hot” Issues

- Augmenting the short term pipeline
- Getting the present cost structure under control, while shifting to a more variable cost base
- Identifying then managing real strategic assets, technologies and platforms for maximum value
- Embedding and enriching cross R&D collaboration and interchange
- Placing bets (investments) on key relationships for the future R&D

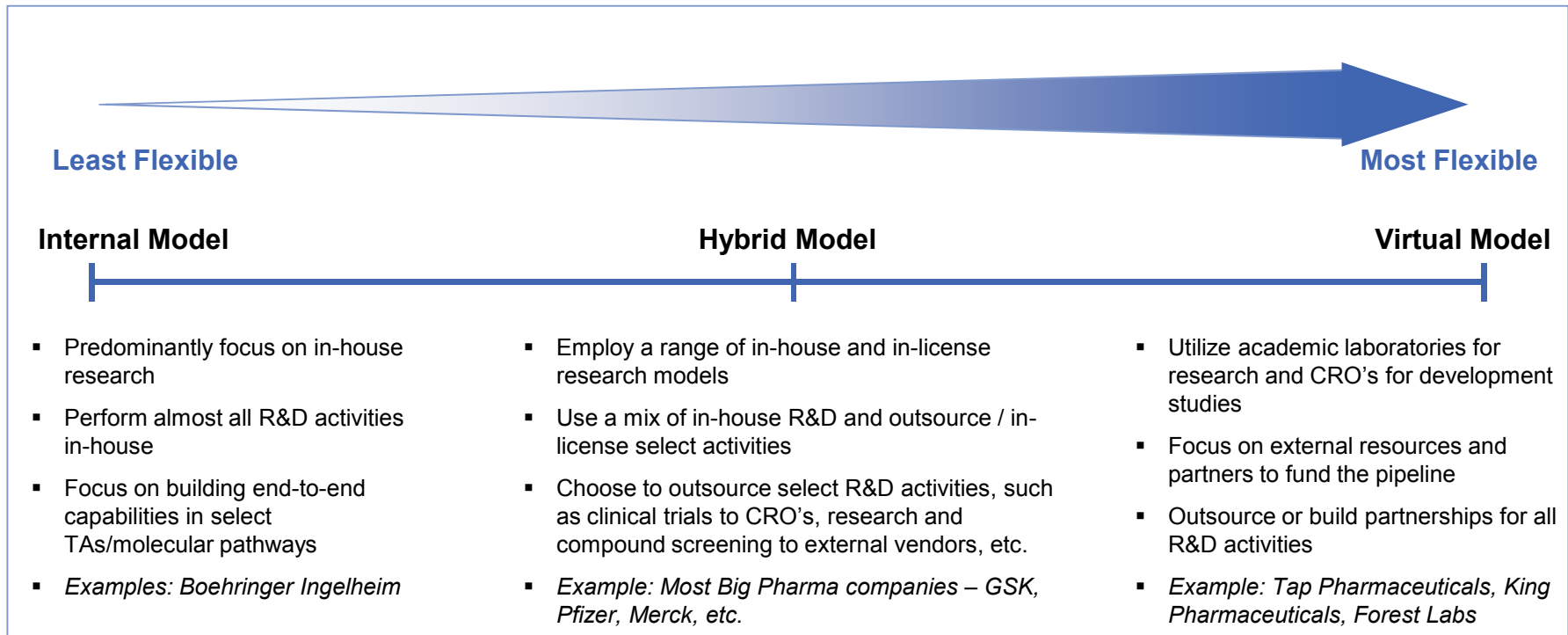


Organizational Constraints

- Large established infrastructure
- Internally focused, largely fixed and interdependent processes
- Culture of ownership and control, not partnership and collaboration
- Mixed competence in establishing and managing external relationships
- Incentive structure focused on internal performance
- Organizational inbreeding with limited non industry input

While many Pharma and Biotech players are moving towards some form of a virtual model, partnering strategies are taking on many forms

A company's strategy and core competencies will help select the appropriate R&D model

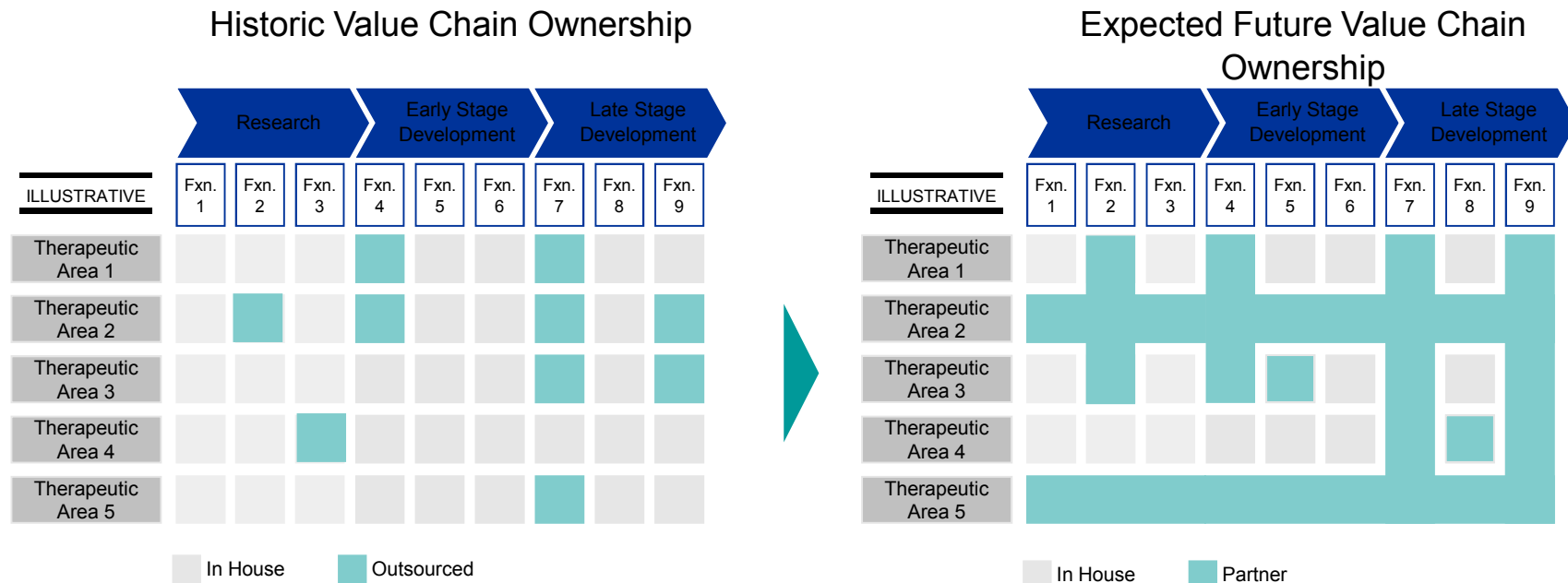


Today, most companies employ some degree of a hybrid R&D model varying on their use of external relationships. Even though companies are increasingly using external vendors, these relationships are being managed by an internal management structure.

Though most companies are hybrid in some aspect there is room to move towards more flexibility by adapting to aspects of a virtual R&D model

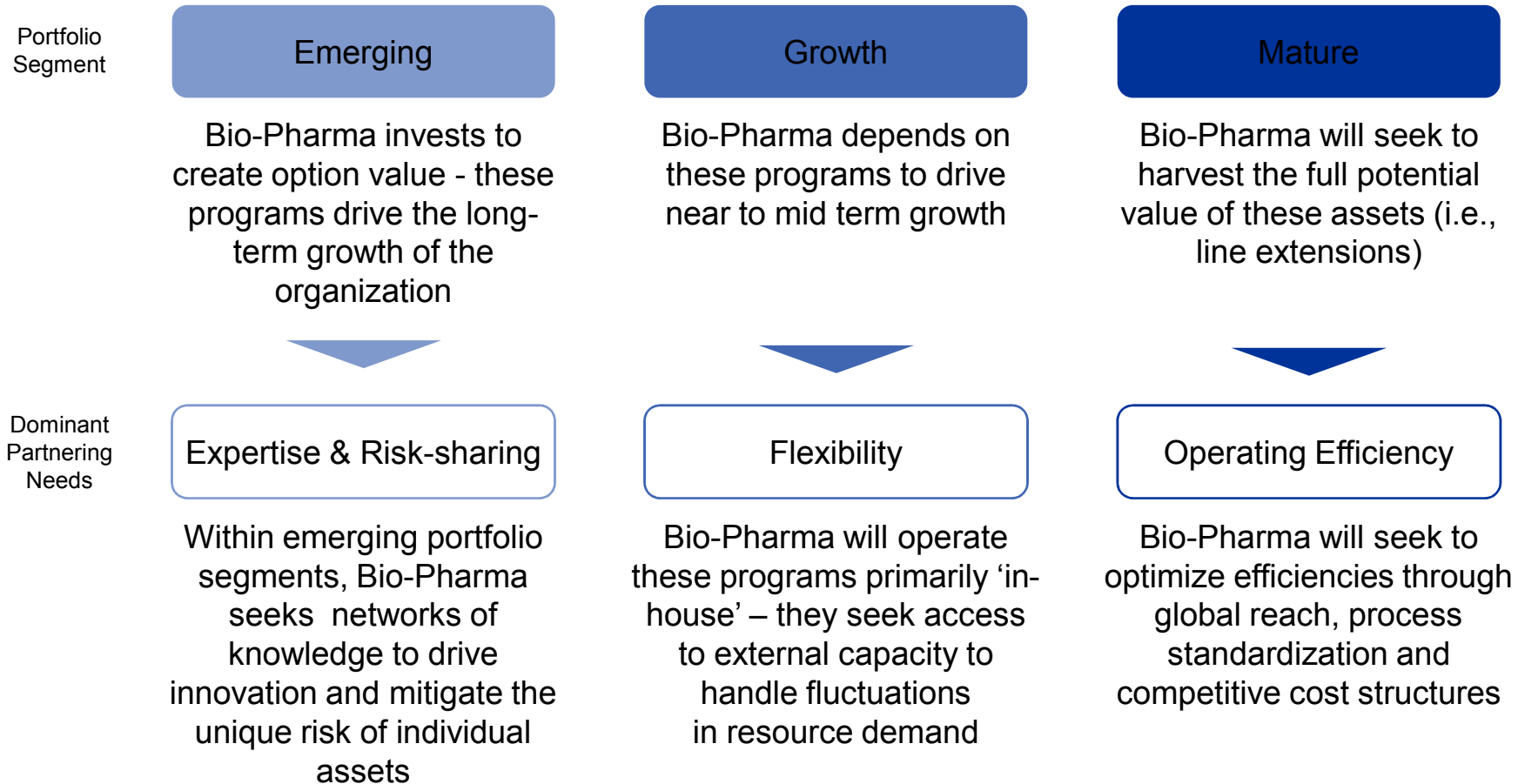
Partnering strategies are taking on multiple forms, with some focused on sourcing functional depth and others aspiring to program-based partnerships

Strategic direction will dictate which therapeutic programs and capabilities are highest priority; for the remainder, large Bio-Pharma will look to collaborate and access capacity in new and creative ways



In general, 'vertical' functional partnerships will evolve in all areas deemed to be non-core, while 'horizontal' programmatic approaches will be applied in select therapeutic programs

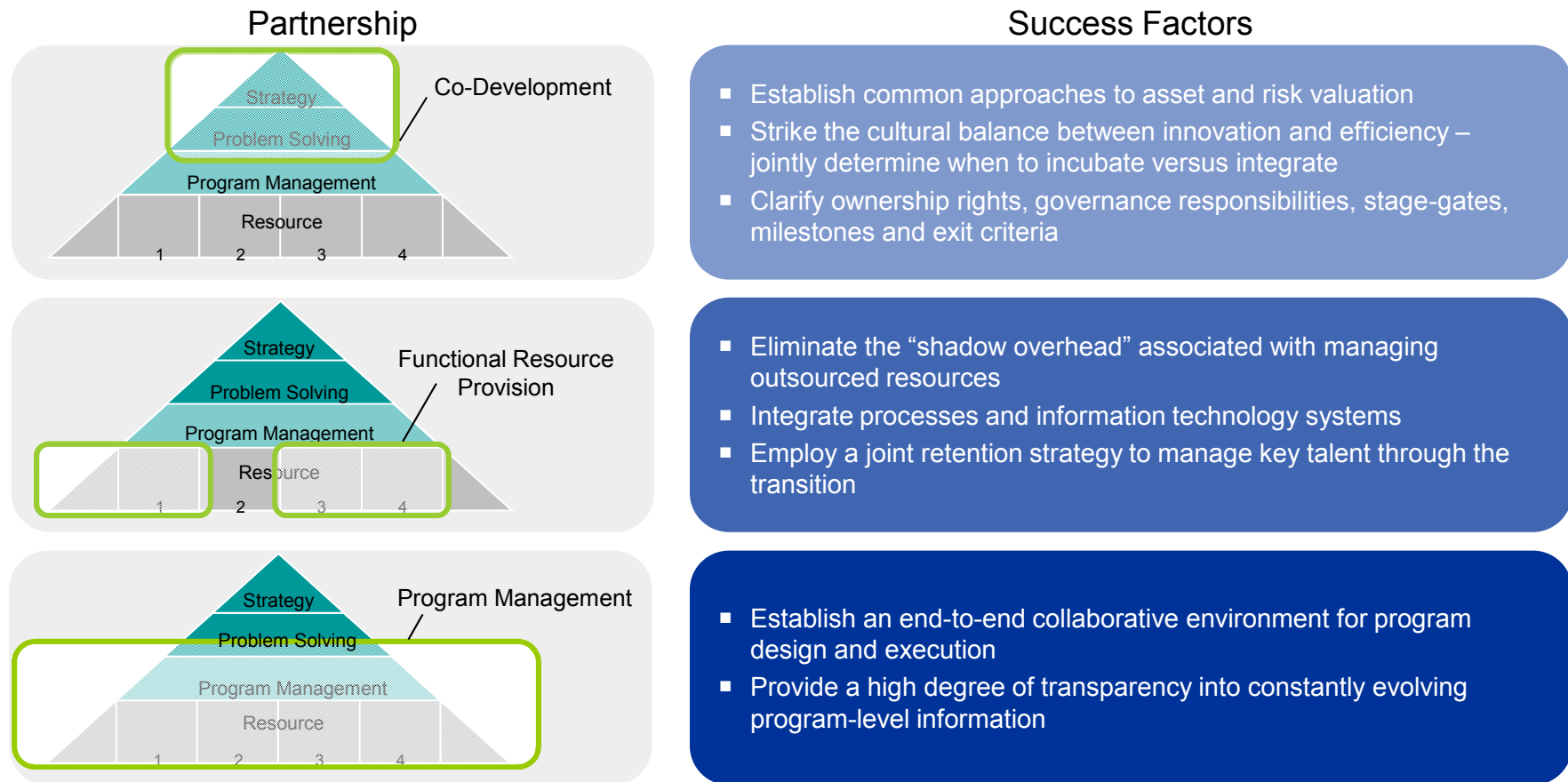
A “portfolio-based” partnering strategy acknowledges that each segment has a unique value and risk profile – therefore the dominant partnering need in each varies



In response, partners must pursue synergies and develop solutions that provide cost-effectiveness, operating responsiveness or knowledge provision, based on their core strengths

While the vision for each partnership model is clear, large Bio-Pharma executives suggest that there are significant execution hurdles that must be addressed

Whether partnering on the basis of knowledge or capacity, both large Bio-Pharma and its partners have to maintain focus on long term value creation and design incentives to support mutual objectives



Diagrams represents a drug discovery and development program-level capability framework. Partner contributions are highlighted in green

Bio-Pharma leaders must take a greater degree of ownership in the success of its partnerships and commit the investments required to create a vision, relationship and capabilities together with its partners

Despite many unique “growing pains”, most study participants agreed that successful execution depends on leadership commitment and ongoing, proactive management

Leading Practices in Executing Strategic Partnerships

Commit at the highest levels of the organization

- Engage senior leadership in defining the strategy to avoid the pursuit of tactical objectives at the expense of the broader portfolio
- Articulate a clear vision that links to broader business goals and is promoted throughout the organization

Know your core needs and objectives

- Establish explicit objectives, requirements and incentives to build arrangements that reward targeted outcomes and minimize the amount of transactional incentives
- Consider the future and determine how a partner may serve to enable, and potentially hinder, long-term objectives

Manage partnerships to achieve outcomes

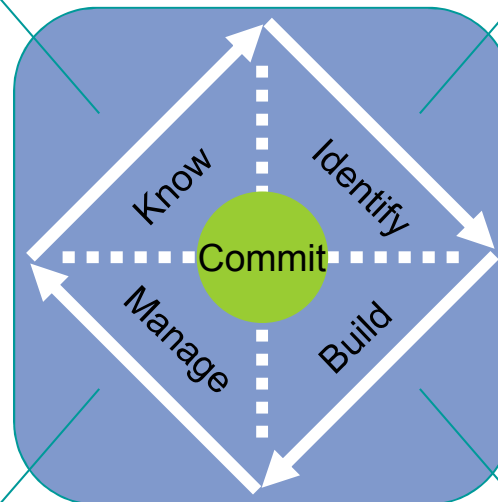
- Manage partnerships as an operational line unit, outside of procurement and ensure the management support
- Manage partnerships with a dedicated and centralized team of resources initially, with the goal of diffusing responsibility over time

Identify the right partners

- Develop a holistic approach to partner selection - look beyond price as the single criterion
- Recognize that partnerships evolve and that partners may not be ready to deliver on “Day One”

Build a mutually beneficial relationship

- Invest sweat equity up-front to jointly build the capabilities that will serve as the foundation for a mutually beneficial long-term partnership
- Build a culture of continuous improvement in both organizations, focus on performance measurement and best practice identification and sharing throughout both organizations



Elements of the Future R&D Model

- In the future existing Pharma Companies and NewPharmas will be characterized by a more variable cost structure, and most importantly, a different, more flexible R&D organization.
- The future R&D model will need to:
 - Be agile, flexible and highly innovative – to compete effectively in the changed landscape
 - Establish the following core R&D capabilities
 - Disease Specific units
 - Virtual R&D Processes
 - Technology and Knowledge Management
 - Deal Making (platforms and Products)
 - Possess multiple knowledge bases required to cover both Small and Large Molecule Science, Infectious Agents, Vaccines and Platform Technologies
 - Effectively manage virtual networks and collaborative communities needed to facilitate and support a flexibility R&D model, access to knowledge on technology platforms and concepts

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