

The Challenge of Enabling Continuous Improvement and Innovation Capability in Pharma R&D

Celia B. Banks, Ph.D.

Director, Organization Development-
Continuous Improvement and Innovation
February, 2013

Presented at IQPC, London, UK
Driving Productivity in Pharm R&D

Agenda of Topics

- **Introduction**
 - **About the Speaker**
 - **Contextual Background of Presentation**
 - **Purpose and Objectives**
- **Perspectives of CI, Innovation and Organization Capability**
 - **What is CI?**
 - **What is Innovation?**
 - **What is an Organization Capability?**
- **Fitting CI and Innovation in the Drug Development Life Cycle**
 - **Root Cause Analysis of Key Issues in Development Innovation**
 - **R&D End-to-End Process Optimization**
 - **Examples of Innovation in Development**
 - **Address Challenges in Creating a CI and Innovation Culture**
- **Recommended Roadmap for a Lean Innovation Capability in Pharma R&D**
 - **Assess -> Define -> Change Plan -> Socialize -> Govern**

Introduction

About the Speaker



- **Joined BMS in 2012 as Director of Organization Development, Continuous Improvement and Innovation. Role supports enterprise-wide Continuous Improvement and Innovation initiatives**
- **Prior to joining BMS, led the CI and Learning & Development Program at Pfizer**
- **Prior to Pfizer, contracted by Toyota Motor Sales as Program Manager for the Discovery phase of the Vehicle Supply Chain Renovation**
- **Selected to serve as a 2011 and 2012 Board Examiner for the Malcolm Baldrige National Quality Award Program**
- **Possess a philosophical doctorate in Human and Organization Systems; a Masters in Organization Development; an MBA; and a Masters in Applied Statistics. Certified as a Quality Manager in Organizational Excellence by the American Society of Quality and as a Lean Six Sigma Black Belt by Villanova University**

Introduction

Contextual Background of Presentation

- February 2007 Bloomberg Businessweek article on Six Sigma versus Innovation. Basic points were:

6σ

- Low Tolerance for Risk...
 - Six Sigma is designed to impact more efficiency and productivity into a company's systems...
 - Focus is on operational excellence and on doing things right
 - Six Sigma fosters a very low tolerance for risk because risk increases variation
- Innovation Equals Change...
 - Innovation seeks to brave undiscovered, uncertain territory
 - Fledgling efforts are inherently inefficient as they ramp up
 - When design methods are deployed to reframe the problem, innovation seeks to do the right thing

Game
Changing
Δδ

Introduction

Contextual Background of Presentation

- April 2004 [ePrint 2011] Harvard Business Review article by C. O'Reilly III and M. Tushman on The Ambidextrous Organization stated the reality that...
 - A business culture that emerges once the former has taken root – i.e., getting grounded in Six Sigma – will be hostile to the growth of the latter – i.e., Innovation
 - Obviously, we need both!!

6σ + Game Changing
 $\Delta\delta$

Introduction

Purpose and Objective

- **The purpose of this presentation is to discuss the challenges of enabling a culture of Continuous Improvement and Innovation in pharma R&D**
- **Objectives are to:**
 - **Provide insight in perspectives of CI and Innovation**
 - **Identify challenges and offer explanation through Root Cause Analysis**
 - **Recommend a roadmap for pharma R&D to embrace the seemingly ambidextrous nature of CI and Innovation**

Perspectives of CI, Innovation and Organization Capability

What is Continuous Improvement?

- The American Society of Quality defines Continuous Improvement as:
...an ongoing effort to improve products, services or processes
- ASQ distinguishes between the terms *Continual* and *Continuous*
 - *Continual* improvement is a broader term coined by W. Edward Deming, and it encompasses a general process for improvement including 'discontinuous' improvement
 - *Continuous* improvement is a subset of *Continual* improvement

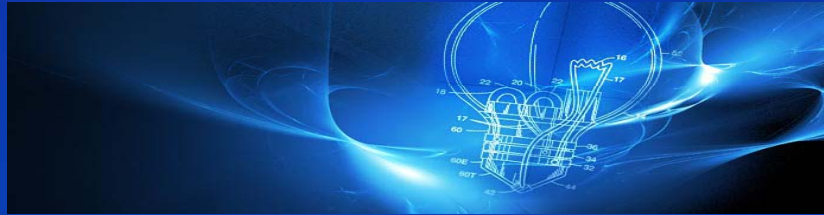


Perspectives of CI, Innovation and Organization Capability

What is Innovation?

- Dictionary.com provides a succinct definition for Innovation:

Something new or different introduced



- This simple definition offers two camps to explain the evolution of Innovation
 - One camp is that through some radical output that disassociates what was and what will be
 - A second camp is that through the effort of improving what was, we discover a new way of looking at it, and this new way transforms what was into what will be
- We deduce, then, that Innovation occurs by way of
 - Radical or game changing thinking
 - Continual improvement

Perspectives of CI, Innovation and Organization Capability

What is an Organization Capability?

- Organizations customize the meaning of Organization Capability to fit their culture/needs...
 - A succinct business perspective describes it as a way to gain competitive advantage through people, processes, technologies, financial, and strategic intent -- the integration of organization systems
 - Organization Capability assumes a link between effective resource management and an organization's competitiveness (ability to be competitive)
 - Another assumption is that people resources possess the right competency for which capabilities will be developed
 - The takeaway from any organization's definition of its capability is that building competitive advantage relies on *people doing the right things right*

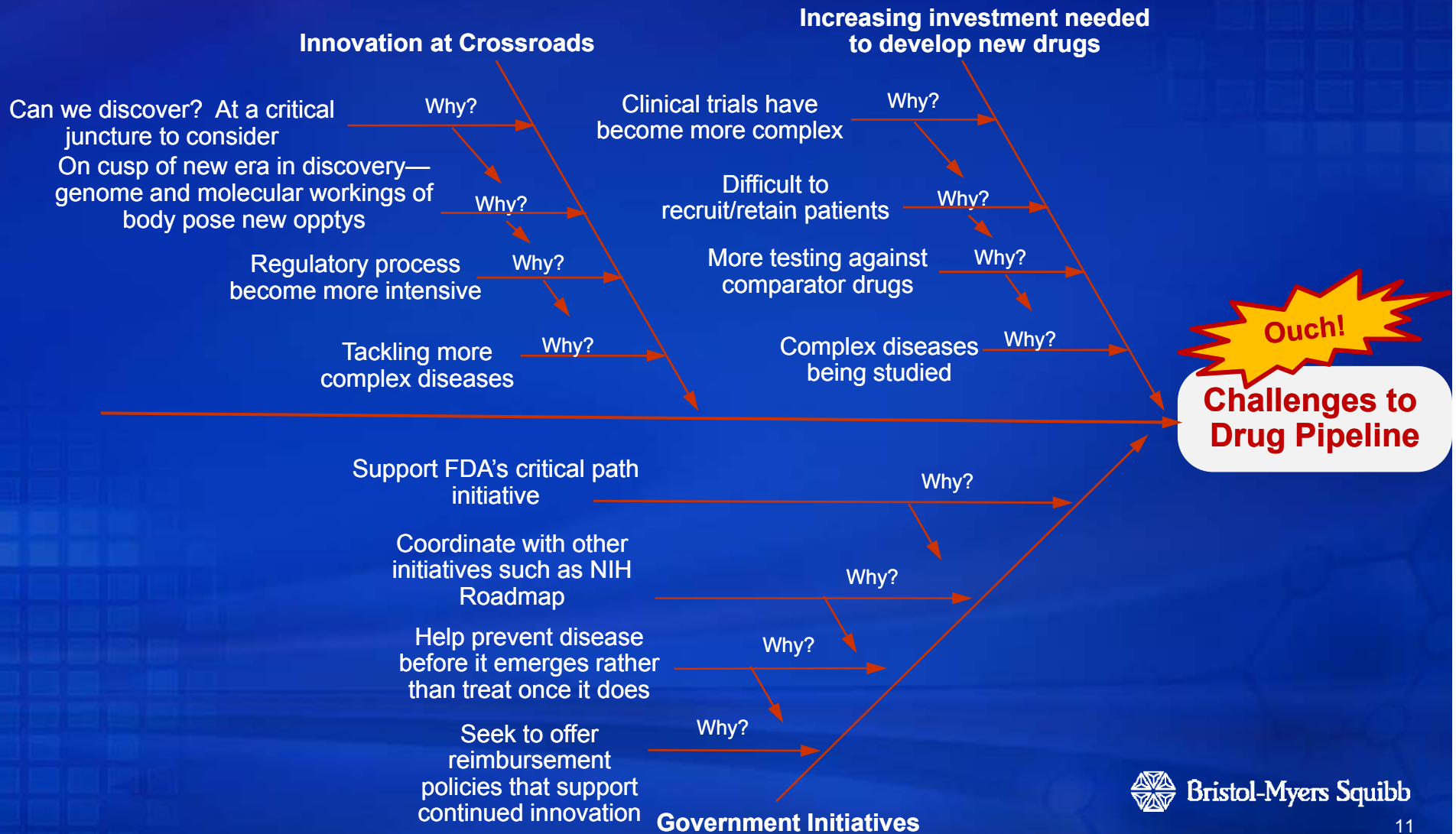


Fitting CI and Innovation in the Drug Development Life Cycle

- **Key issues challenging today's drug pipeline**
 - **Pharma R&D involves substantial risk because the nature of scientific research is inherently uncertain...**
 - **Once medication is approved, the commercial success rate of Pharmaceuticals is low**
 - **BioPharma has a disproportionately large R&D investment footprint**
- **Why?**
 - **Increasing investment is needed to develop a new drug**
 - **Innovation is at a crossroads in pharma discovery**
 - **Government initiatives**
- **Help is on the way...**
 - **Public-private partnerships to “share” research costs**
 - **Incremental innovation will bring in reinvestment dollars**
 - **U.S. Government has an eye on preserving incentives for Innovation**

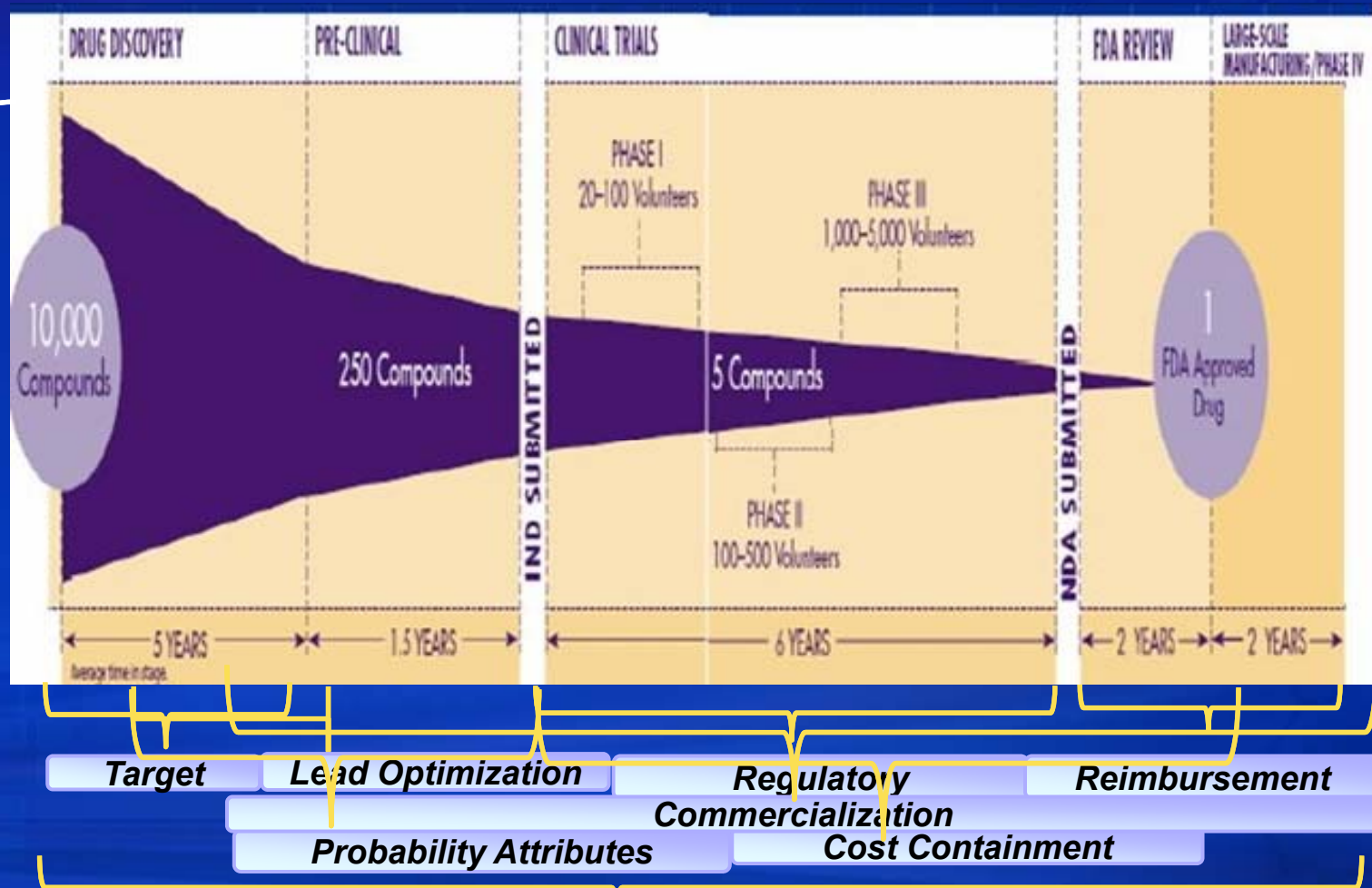
Fitting CI and Innovation in the Drug Development Life Cycle

Root Cause Analysis for Key Issues in Development Innovation



Fitting CI and Innovation in the Drug Development Life Cycle

R&D End-to-End Process Optimization*



Goals are to Reduce risk and Innovate for shorter lead time, more certainty in pipeline

Optimization Levers for Breakthrough Innovation

Fitting CI and Innovation in the Drug Development Life Cycle

- In business, Innovation is for competitive advantage. However, for drug development, while that notion somewhat applies to Pharma, it is sidelined during discovery in order to remove perceived constraints that can derail purposeful brainstorming for novel therapies in patient care
- At Pfizer, R&D used the term *Innovation engine* to refer to the selection of ideas that supported the drug pipeline. The ideas that fed into the “engine” were intended to thrust the organization forward in its ability to deliver products
- The engine reference has some merit as Innovation does not really start and proceed in the air...it actually follows a process which matures into an iterative cycle:



Fitting CI and Innovation in the Drug Development Life Cycle

Time Series Examples of Innovation in Drug Development

2000	Antibody chemotherapy offers a new approach to cancer treatment
2001	Approval of third class of HIV drugs that target the transcriptase enzyme
2001	Selective aldosterone receptor antagonists offer new class of blood pressure treatment
2002	Human genome is mapped
2003	New way to treat metastatic cancers
2004	First vaccine for prevention of cancer
2006	New class of HIV medicines
2007	Treatment for Huntington's disease
2008	Treatment for non-Hodgkin's lymphoma
2009	Treatment for Multiple Sclerosis
2010	Treatment for Lupus
2011	Treatment for Lupus
2012	Disease-modifying treatment for Cystic Fibrosis

Fitting CI and Innovation in the Drug Development Life Cycle

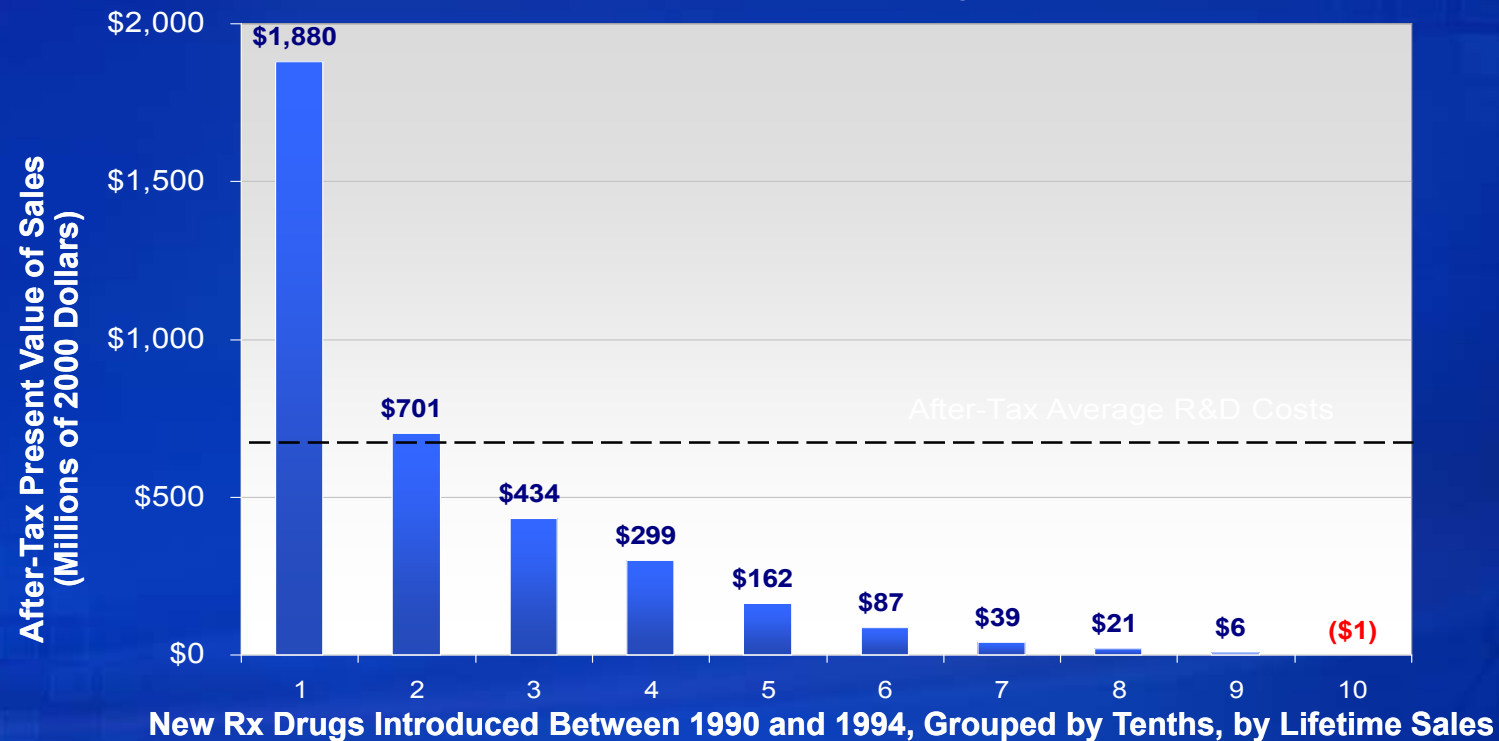
Address Challenges in Creating a CI and Innovation Culture

- Gaining consensus for a common language around how CI and Innovation are defined throughout the organization
 - CI has many labels such as operational excellence, process excellence, Lean, Lean Sigma, etc.
 - Innovation is not limited to process optimization, could be discovery of new drugs
- Ensure that Innovation touches across the entire organization, and is not just top-down or bottom-up
- High risks and failure potential creates stagnation in the commercialization process
 - Need collective thinking of how to innovate in this space
- Organization needs to have a process for allocating resources on Innovation initiatives
 - Identify a reward system to motivate the organization
 - Gain cooperation on cross-functional/enterprise initiatives
- Establish how you will evaluate the performance of CI and Innovation efforts
 - Consider value driven outcomes like ease of use for patients or employee satisfaction in making it easy to get work done
 - Do not track solely by cost savings

Fitting CI and Innovation in the Drug Development Life Cycle

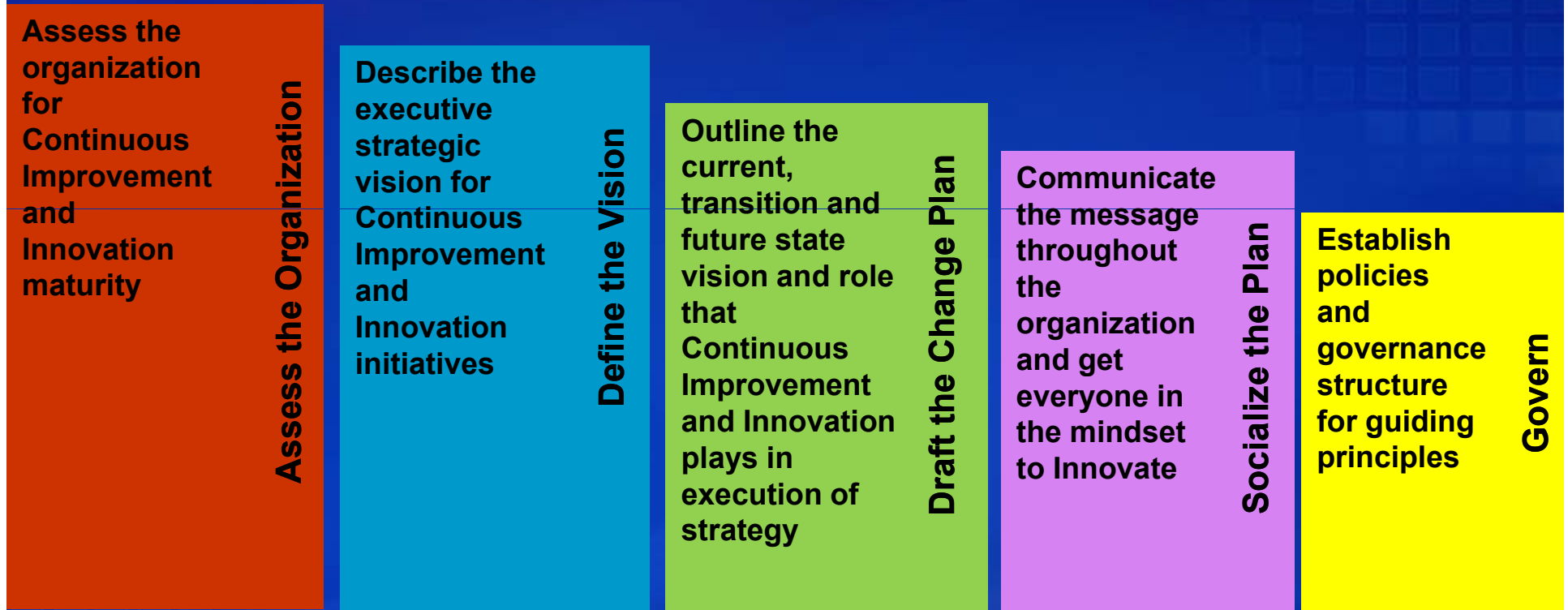
Address Challenges in Creating a CI and Innovation Culture

Few Drugs Succeed Commercially Even After Approval:
Lifetime Sales Compared to Average R&D Costs



Source: DiMasi, J. and Grabowski, H., "The Cost of Biopharmaceutical R&D: Is Biotech Different?,"
Managerial and Decision Economics, 2007.

Recommended Roadmap for a Lean Innovation Capability in Pharma R&D



A Lean Perspective...



Session Wrapup

Q U E S T I O N S
A N S W E R S

Q & A

Thank You!