



Redefining Success for Life Science Projects

Tarja Mottram, CEO
July 27, 2010

***m*Scholar**

ACTION  FOR RESULTS.

Welcome to “Redefining Success for Life Science Projects”

Presenter

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CEO, Action for Results, Inc.



Hosted by



www.actionforresults.com

“Connecting Strategy & Execution for Healthcare Innovation”

www.mscholar.com

“Learning Solutions for Increased Project Performance”

Before We Begin....

- **Submit Questions as we go along**
 - Click the "?" icon at the lower right corner of your screen to bring up Q&A panel where you can type and submit questions.
 - There will be time for questions at the end of the presentation.
 - We may not be able to answer every question but will focus on the most representative.
- **PMI / PDUs**
 - 1 PDU
 - PMI reference number will be sent to attendees in a follow-up email along with a link to download this presentation.
- **Boston BioPharmaPM September Conference**

Boston BioPharmaPM Conference

September 21, 2010 Reggie Lewis Center, Boston, MA

“Delivering Value Through Projects”

- Leaders from top Life Science companies will discuss why project management is one of the most important capabilities for competitive advantage, how it's defined differently from other industries, and how it will evolve as a result of the industry trends.
- Conference speakers include:
 - Mike Bonney, CEO, *Cubist Pharmaceuticals Inc.*
 - Maryann Ciampa, Director, Office of Program Management and Services, *Becton Dickinson Diagnostics*
 - Rosemarie Day, former COO, *Commonwealth Health Insurance Connector Authority*
 - Rich Maltzman and David Shirley, authors, *Green Project Management*
 - Ron Rammage, Engineering Manager Software, *Abbott Medical Optics*
 - Dee Suberla, Senior Program Manager, *Baxter Pharmaceuticals & Technologies*

“Delivering Value Through Projects”

- Learn how to redefine project success criteria by understanding the difference between delivering a product and delivering long-term sustainable value to the business and customers.
- Gain insight into practical and proactive techniques for building and executing effective program and project plans, including how to overcome some of the toughest challenges in building and maintaining a realistic schedule under pressure, and delivering a quality product to market.
- **Early Bird Special Extended Through August 31st!**
 - *BPPM Members:* ~~\$299~~ **\$249**
 - *Event & BPPM Membership:* ~~\$339~~ **\$289**
 - *Non-Members:* ~~\$359~~ **\$309**
 - *Groups of 3 or more:* **20% Off**

**For More Information and for
a Downloadable Brochure, Visit**

www.mscholar.com/bppmboston

Learning Objectives for Today

- Examine the pitfalls of traditional project success criteria and the strive to move to outcomes-based success measures.
- Provide a systemic framework that will help you plan for project success.
- Identify the most common mistakes that result in project failure.
- Gain helpful hints for removing behavioral and organizational obstacles to “doing the right thing.”



Outline

- Defining Program & Project Success
 - Traditional definition
 - Outcomes-based criteria
- Project Success Framework: Planning for Success
- The Top 3 Mistakes that Have the Biggest Impact on Outcomes
- What To Do To:
 - Get your team to own the outcomes, not just deliverables
 - Transform heroic acts into sustainable performance
 - Change management behaviors that hinder success
- Questions & Answers

Completing a Project

≠ Project Success

**Completing a Project On
Time and Within Budget**

≠ Project Success

**Completing a Project Ahead of
Schedule or Under Budget**

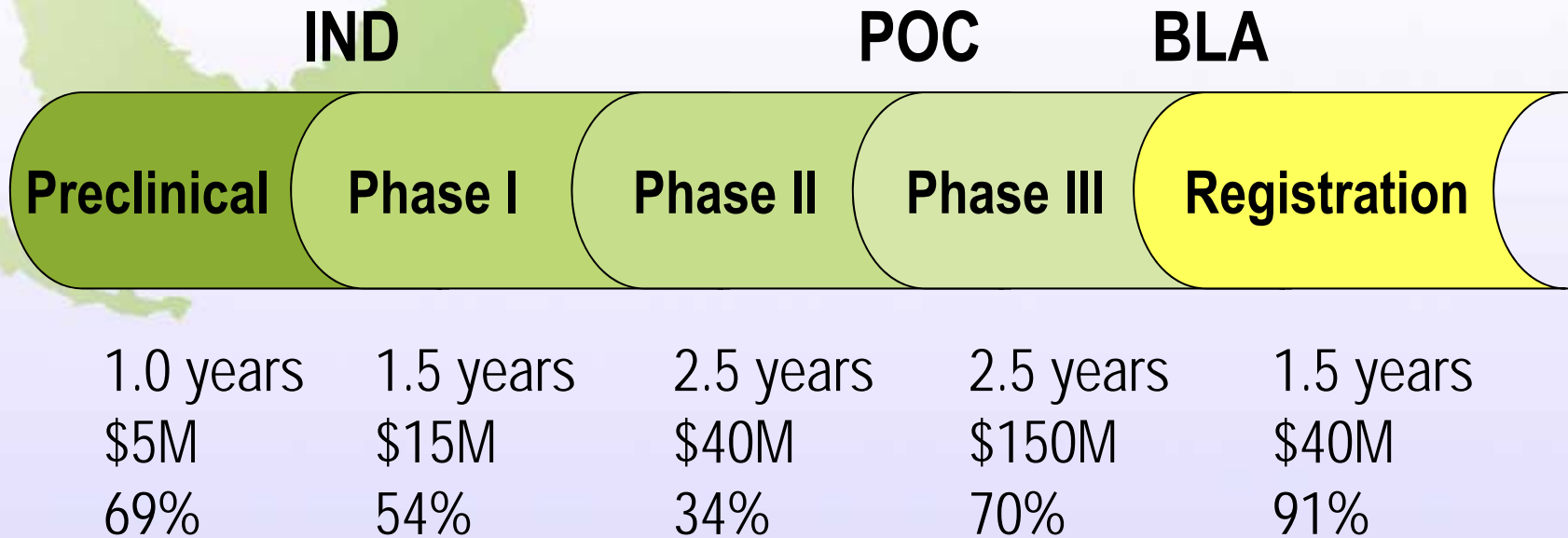
≠ Project Success

Outcomes Driven Definition

**Completing a Project Within
Acceptable Variance of Schedule
and Budget *and* Delivering
Measurable and Sustainable Value
to Customer and/or Business**

= Project Success!

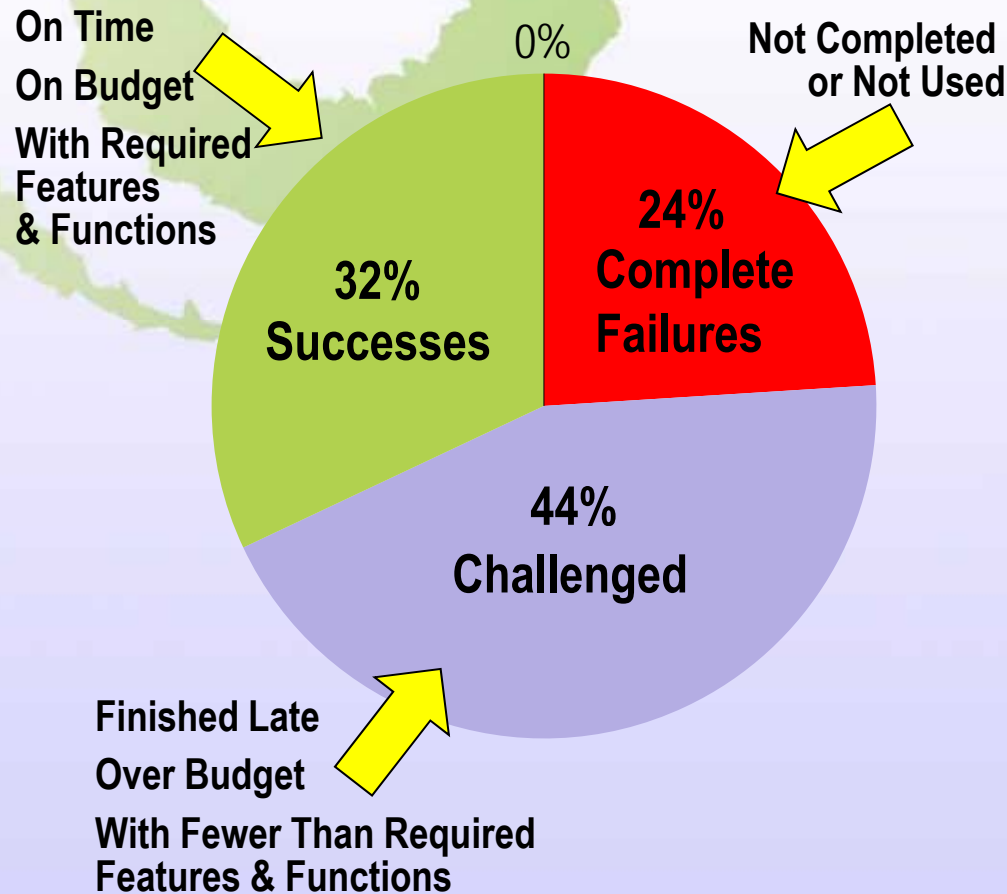
Confronting Brutal Reality...



Biopharmaceutical Development: Time – Costs – Success Rates

Source: Nature Reviews Drug
Discovery, Vol.9, 203-214 (March 2010)

Confronting Brutal Reality...



*From Standish Group, June 2009
Chaos Report on IT/Software Projects*

The IT project statistics also apply closely to Medical Device Industry:

2 out of 3 projects are failing!

If Your Business Success Depends on Projects, Is This Acceptable?

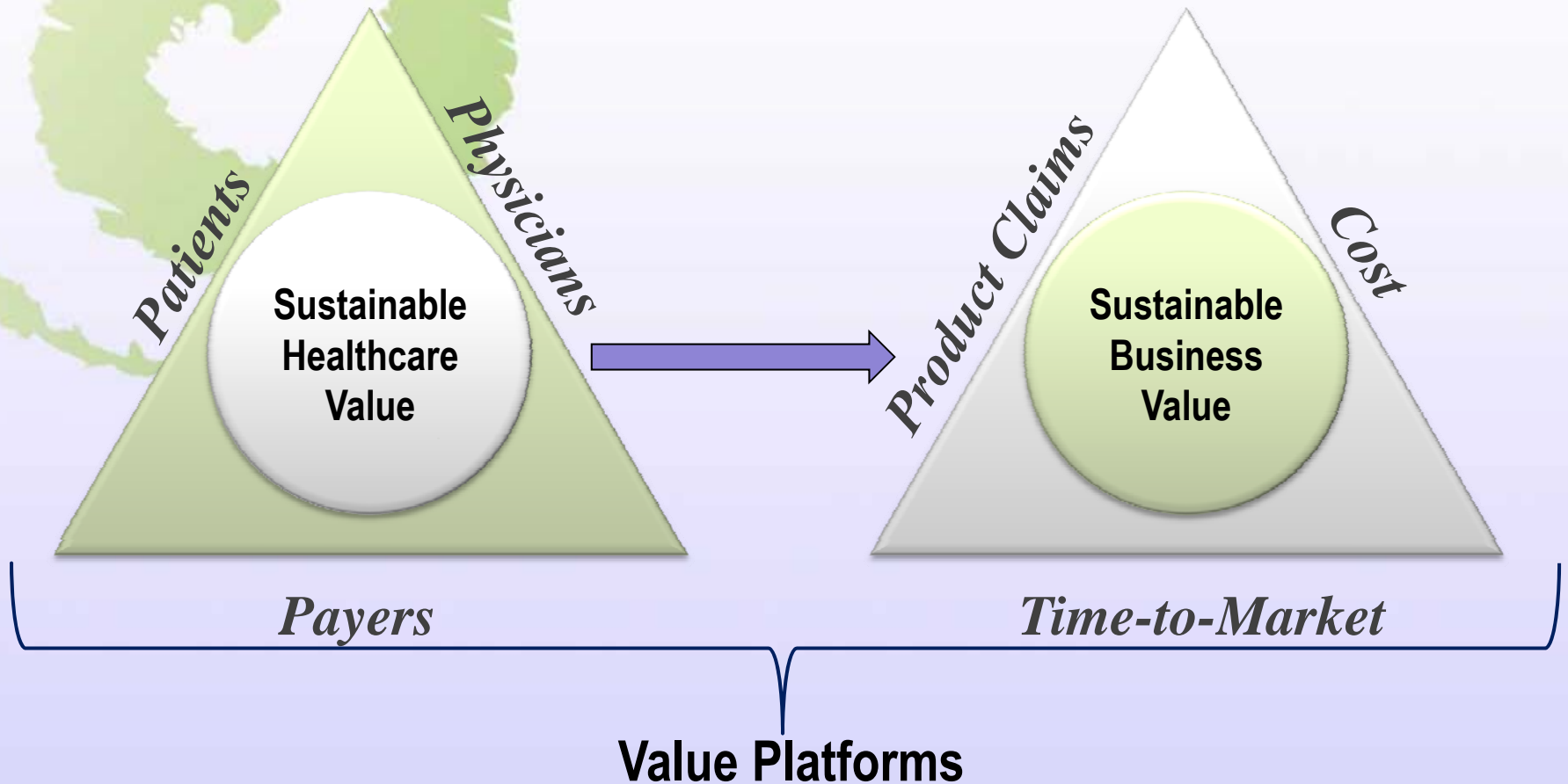
What Does It Mean to Deliver Sustainable Value to Customer?

- “Differentiated products will be those that address the unmet medical needs while meeting the additional emerging profiles of patients, payers, providers and regulatory agencies – globally, including traditional and emerging markets – to achieve ultimately the optimal label and pricing and positioning.” (Accenture, 2010 report on Shaping the Future of Pharmaceutical R&D)
- “Strong value propositions should offer tangible results and answers to critical issues faced by customers and payors.” (European Forum on Life Science Futures)
- “Medical-device companies that understand the environmental challenges and embrace sustainability prior to the development of industry environmental requirements will potentially have a competitive advantage.” (Medical Design & Engineering: “MD news”)

What Does It Mean to Deliver Sustainable Value to Customer & Business?

- Understanding new, emergent market needs: listening to a **range** of voices – globally
- Improving the company's reputation, depth and breadth (along a value chain) in a way that draws more customers
- Moving from short-term bottom-line valuation (quarterly earnings focus) to understanding the opportunity costs and return gained from building solutions to systemic problems
- Better, smarter, more relevant products

Strategic Value Creation

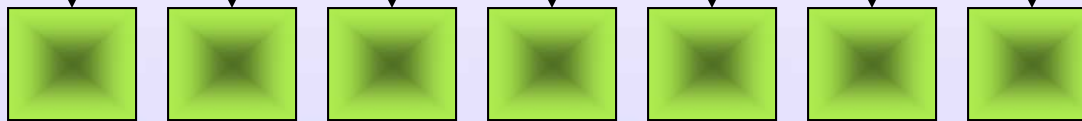


- Maximize patient benefit
- Improve/advance treatment outcomes
- Result in higher healthcare value (pharmacoeconomics)
- Result in more socially and environmentally responsible solutions
- Compete on value (not price)

Product Management

Program Management

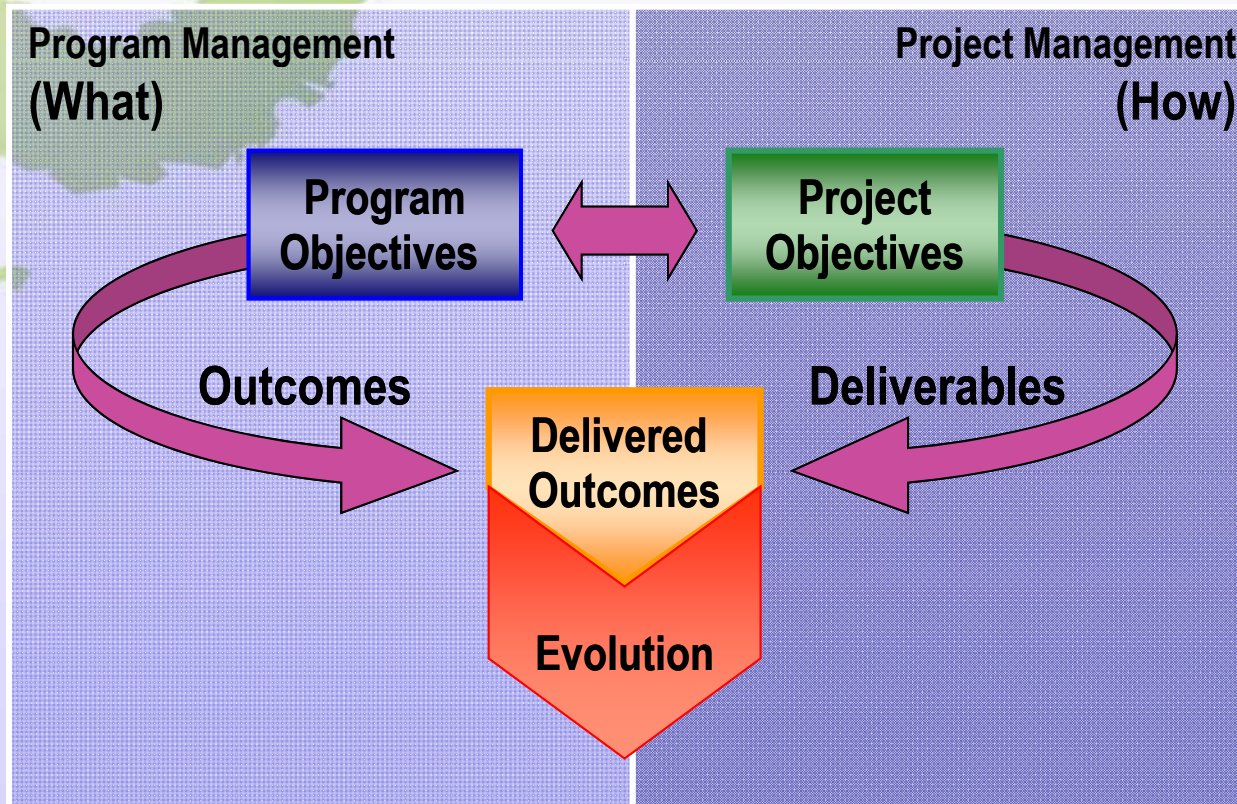
(i.e., range of compounds or related treatments, regional variations, new dosage forms...)



Project Management



Program Management = Outcomes Management



Top 3 Mistakes that Impact Project Outcomes the Most

- 1. Poorly Defined and/or, Insufficient, or Incomplete Requirements**
- 2. Lack of Cross-functional Commitment and Pathway for Shared Delivery of What Was Promised**
- 3. Too Many Projects Pulling the Same Resources at the Same Time.**

Plan for Success:

No Plan = No Control

No Control = Shooting in the Dark

Not in the plan → Don't work on it

In the plan but not adding value → Take it Out

Planning for Program & Project Success



Clarify Desired Outcomes & Align Strategies to Get There

Typical Problem(s)	How to Recognize the Problem
<ul style="list-style-type: none"> • Project gets initiated without a clear understanding of why it should be done, how it will contribute to business strategy, or what priority level it deserves compared to everything else. • A project that is already under way suddenly finds itself “lost” when new challenges are encountered, senior management steps in, and the team is no longer in charge. 	<ul style="list-style-type: none"> • Deliverables are slipping because people are pulled into other priorities and can’t stay focused. • Executive attention varies from “out of my radar screen” to micromanaging, depending on urgency and noise in the system. • Project is cancelled, or budget and/resources are cut. • Lack of urgency and ownership for desired outcomes.
Do	Don’t
<ul style="list-style-type: none"> • Develop a clear, risk adjusted business case early on and maintain it through the life of the project. • Be clear about: <ul style="list-style-type: none"> • The problem you’re trying to resolve (unmet needs, and sense of urgency) • How resolving the problem will set your business apart and why it will be worth doing (opportunity cost) • Development scenarios, risks and strategic options • The real value drivers for your product (and get everyone to buy into them!) • Obtain cross-functional senior management commitment to the business case, priorities and trade-offs --- at the start and on-going as changes, risks and issues arise! 	<ul style="list-style-type: none"> • Jump into tactical planning before the strategy is clear and well aligned on all levels: <ul style="list-style-type: none"> - business & product and/or therapeutic area strategy - program/project strategy - functional strategies (regulatory, clinical, mfg, etc.) • Ignore the need for ongoing strategic alignment at the senior mgmt level: Are your core team members helping align functional priorities and strategies? Should you have a Strategic Advisory Committee to gain senior management alignment and proactive guidance? • Become victimized: Define gaps and implications, and recommend alternatives.

Use Process to Improve Deliverables & Outcomes

Typical Problem(s)	How To Recognize the Problem
<ul style="list-style-type: none"> • The team gets invested into a product design and/or solution before they know what's needed for the "most value" to customer and the business. • Compliance gaps that get discovered in design reviews or, worse, after launch... OR... the team gets bogged down by a rigid process & develops a checklist mentality. 	<ul style="list-style-type: none"> • Frequent "late stage" changes due to new requirements. • Unexpected increases to schedule duration and/or cost. • Finger pointing between team members. • Poor predictability <i>or</i> "the project <i>never</i> ends...." • No way of knowing if the project delivered what was intended.
Do	Don't
<ul style="list-style-type: none"> • Build voice-of-the-customer and customer validations into the requirements management process. • Ensure proactive VOB* input defining requirements, priorities, and plans. • Document requirements and make sure that your testing and validation plans reflect them. • Establish robust cross-functional sensing mechanisms and communications that alert the team to external trends & requirements. 	<ul style="list-style-type: none"> • Lose your brain over procedure: get agreement upfront on how to apply the process right to improve predictability of your deliverables! • Keep adding new requirements without understanding their impact: take control by applying change control! • Ignore the need to manage stakeholder expectations: frustrated stakeholders will always work against your goals either directly or indirectly. • Accept a process that has lost its value: improve it!

*VOB = Voice of Business

Plan for Success and then Follow the Plan

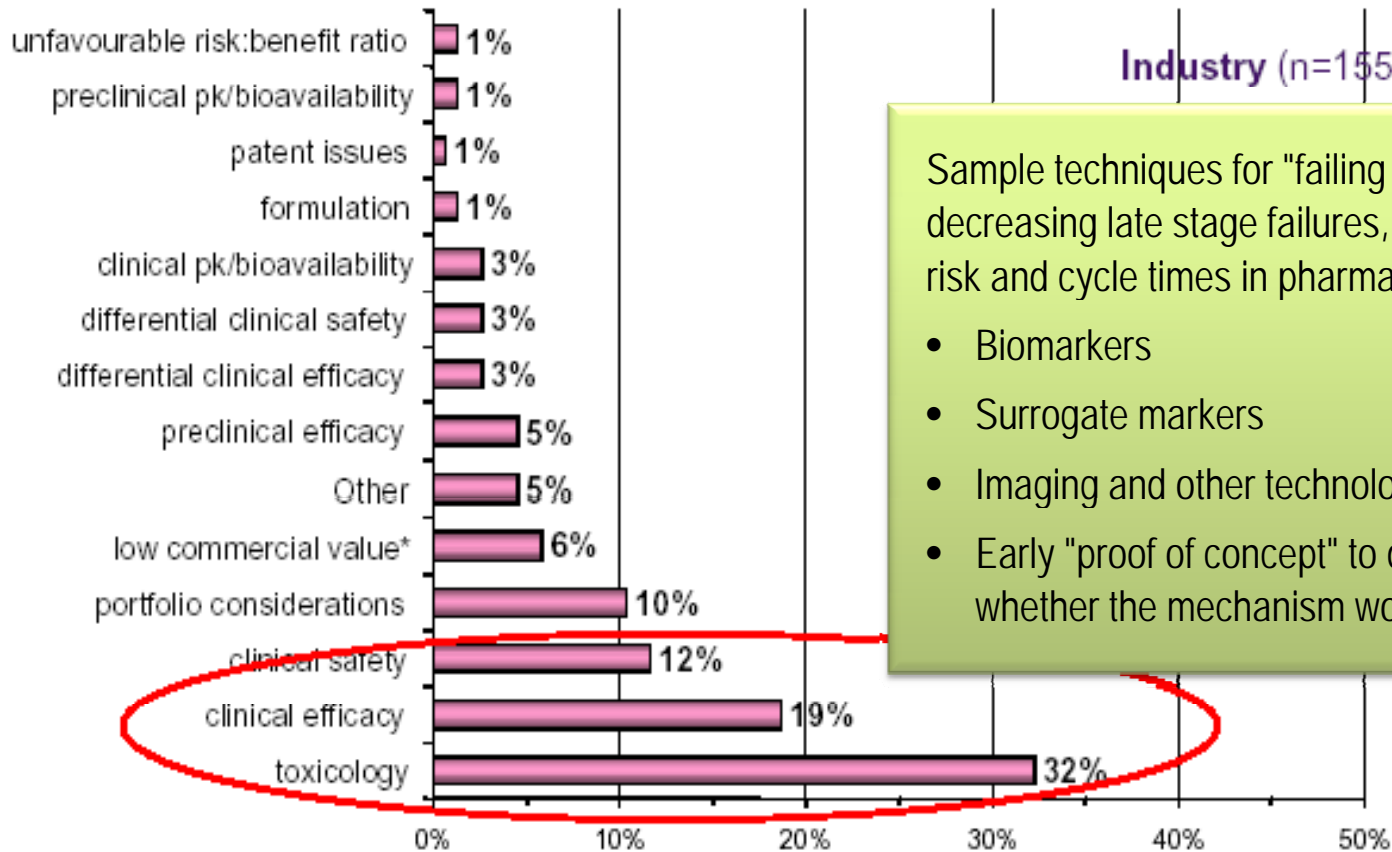
Typical Problem(s)	How to Recognize the Problem
<ul style="list-style-type: none"> • Lack of upfront planning, and cross-functional integration of activities. • Trying to do too many things in parallel. • Best case schedules, not adjusted for risk or realistic resource scenarios. 	<ul style="list-style-type: none"> • Frequent conflicts and issues that create delays, budget overruns, frustration and team burn-out. • Serial problems where one issue suddenly throws off the entire plan and there doesn't seem to be any way to recover. • Angry words of blame when things go wrong, and little acknowledgement of what's going right.
Do	Don't
<ul style="list-style-type: none"> • Develop project strategies and detailed plans upfront with the cross-functional team! • Plan for risk: build critical risks into your schedule! • FTE in a project = 75% planned resource (not 175% !!!). • Optimize the schedule with your team: challenge the team to find ways to deal with constraints – realistically! • Focus on outcomes needed (not just schedule) when defining alternatives. • If you are out of control, develop a recovery plan! 	<ul style="list-style-type: none"> • Say “we’ll make it happen” unless you know how to make it happen. • Submit a schedule without making sure that your team has confidence in being able to deliver it. • Let your plan get outdated: it’s a daily tool for you and your team to stay connected and on track. • Gloss over delays and problems: every meeting needs to assure you of delivery to the plan and/or robust issue resolution to recover if the plan is at risk. (Do you review your issues log every week?)

Reduce Technical Risk As Early as Possible

Typical Problem(s)	How to Recognize the Problem:
<ul style="list-style-type: none"> • Technologies selected have never been used before and risk is downplayed. • Technological evaluation does not consider the full scope and complexity of the proposed solution. • Early stages do not include sufficient understanding of risks, failure modes and effects. • The time for Technology Transfer is underestimated 	<ul style="list-style-type: none"> • Frequent technical issues, such as: <ul style="list-style-type: none"> • Product bugs • Quality issues • Test/product failures • Cost increases during development and deployment. • Unexpected delays and poor predictability. • Late stage clinical failures that should have been predicted.
Do	Don't
<ul style="list-style-type: none"> • Separate technology development and/or discovery from product development (and secure the time & budget for it!). • Perform a comprehensive technical assessment and use predictive tools and techniques early on to pinpoint areas with highest risk. <ul style="list-style-type: none"> • For medical device: mitigate most risks before entry to development. • Understand probability of success and address most difficult trade-offs first. • Manage risks from day one until the end! 	<ul style="list-style-type: none"> • Rush to development: 70% of the factors contributing to product success are established by the time the product is defined. • Try to "go it alone": independent experts can help understand complex technical issues and evaluate solutions. • Lose sight of the business case when evaluating trade-offs and risk responses. • Put all your eggs into one basket: this applies to technical and clinical pathways, claims and regulatory strategies, partners/suppliers, manufacturing lines, and internal resources – "what if" is a start of preparedness.

Primary Termination Reasons for Pharma Projects

Primary termination reason in 2002



Industry (n=155)

Sample techniques for "failing fast"/ decreasing late stage failures, and reducing risk and cycle times in pharma projects:

- Biomarkers
- Surrogate markers
- Imaging and other technologies
- Early "proof of concept" to determine whether the mechanism works

Profile based on NASs terminated in 2002 that had reached any stage of development process between 1st toxicity dose and 1st launch from 34 companies

Percentage of reasons for termination in 2002

Source: CMR International, 2003



Optimize Project Structure for Agility

Typical Problem(s)	How to Recognize the Problem
<ul style="list-style-type: none"> • Inadequate project leadership that results in lack of clear direction and poor management of cross-functional dependencies. • PM and core team members lack the skills and authority to “get things done.” • Sponsor is “missing in action” , acts like a “PM-wanna-be” , or just wants his own agenda taken care of. 	<ul style="list-style-type: none"> • Your team is frustrated and asking for clarity, or it has already given up. <ul style="list-style-type: none"> • “Whatever” attitude • Finger pointing • Lack of urgency and missed commitments; worst case: organizational inertia. • Ineffective decision making and/or poor decision quality resulting in constant revisiting of decisions.
Do	Don't
<ul style="list-style-type: none"> • Establish the right program structure and roles – who does and decides what? • Empower the PM to hold the core team accountable, and establish clear decision guardrails for the team members. • Assign an executive sponsor to all “mission-critical” programs and projects and enforce sponsor accountability and consistent behaviors. • Build partnerships between PM and FMs . 	<ul style="list-style-type: none"> • Tolerate behaviors that are not conducive to the outcomes needed – no matter what the level, the PM needs to confront the tough issues, including behaviors that get in the way. • Ignore performance issues – projects fail fast! • Assume that communications “just happen” without clarifying what, how, who and when: 90% of project team issues can be traced back to communications breakdowns.

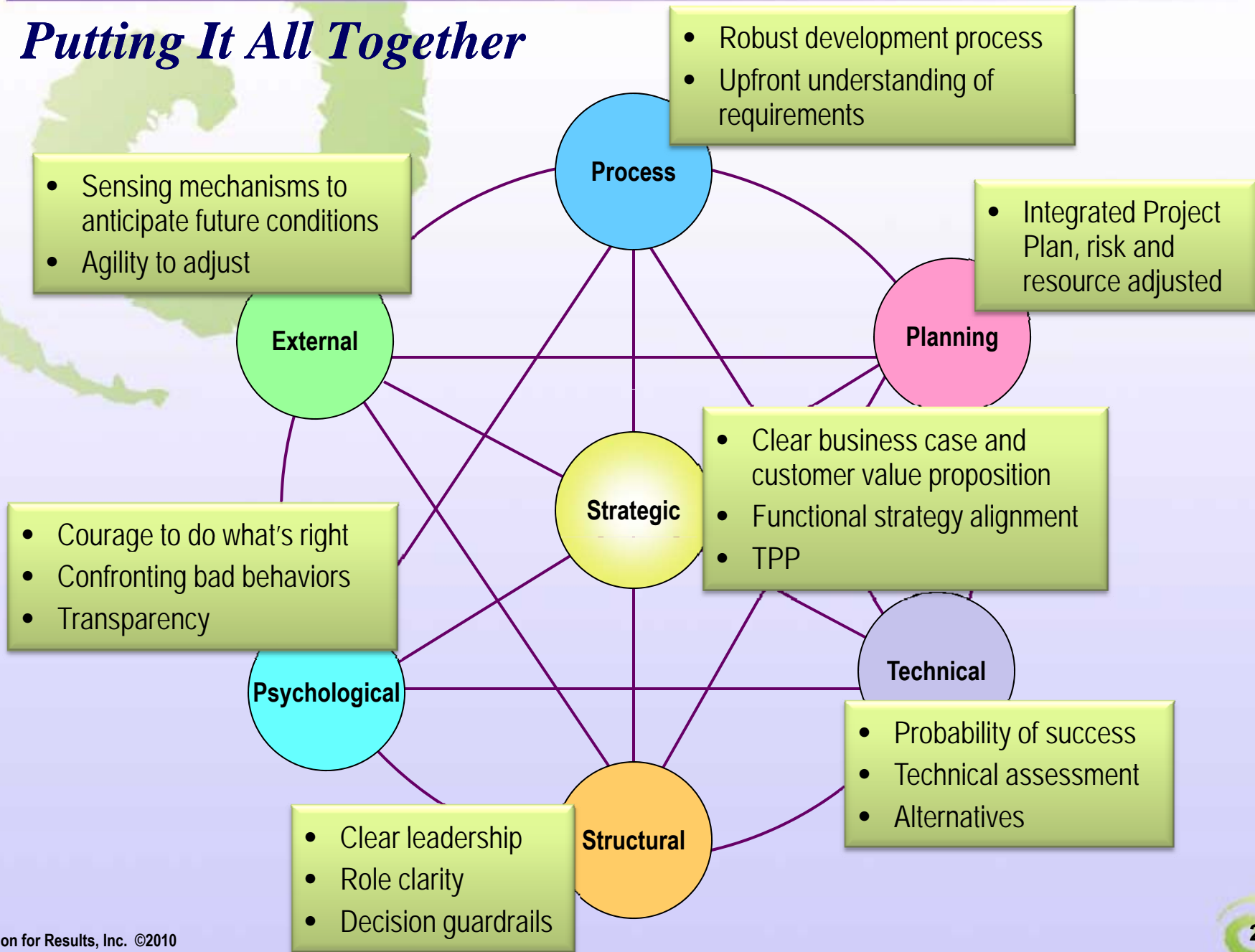
Recognize the Psychological Influence of Culture

Typical Problem(s)	How to Recognize the Problem
<ul style="list-style-type: none"> • Overconfidence that results in promising what's not realistic. • Equating risk management with bad news and not having the courage to address the real risks and impacts. • Management overrules team data and commits to unrealistic plan(s). • Being too short-term focused at the team and business level. 	<ul style="list-style-type: none"> • "You WILL deliver by the date that I promised" (because I said so – and I'll say it louder the next time) • "Frustrated developers syndrome" (FDS) & disempowered team members. • Team and organizational resistance to working together proactively, finding alternatives and resolving issues fast. • Missed milestones, and project/product failures due to cutting corners and not preparing far enough in advance.
Do	Don't
<ul style="list-style-type: none"> • Clarify trade-offs with top management from the beginning: <ul style="list-style-type: none"> • Are you using the trade-off matrix in your charter? • Does your Target Product Profile identify value drivers? • Use outcomes-focused scenarios to increase management openness to alternatives • Enlist your sponsor's support : they can help define strategic business options and work through organizational politics! • Facilitate the right dialogue with the right people and document decisions, rationale, actions and owners, so that no decision needs to be revisited for lack of clarity. 	<ul style="list-style-type: none"> • "Cut corners" (i.e. cutting down testing even if the requirements stayed the same); instead: manage trade-offs! • Downplay the impact of risks and issues when presenting to senior management, but do provide alternatives and recommendations. • Let bad behaviors get in the way; you have to rise above them and help others confront realities that could risk your program.

Anticipate the External Forces that Impact Your Project

Typical Problem(s)	How to Recognize the Problem
<ul style="list-style-type: none"> • We plan the project for today's environment rather than the time of filing, the time of launch, or the time of consecutive market introductions. • The assumptions about external conditions were never validated and turned out to be wrong. 	<ul style="list-style-type: none"> • Changes to requirements at pivotal points, resulting in delays and confusion. • Delivering the "wrong" solution when conditions change → unhappy customers and stakeholders. • "Panic sets in when our 'first' regulatory strategy gets met by a rejection letter... because we didn't anticipate the latest changes in the regulatory environment, and never had a parallel path for responding with additional data if needed."
Do	Don't
<ul style="list-style-type: none"> • Identify "organizational sensing" mechanisms that allow you to anticipate future trends (i.e., legal, market, regulatory, technology, scientific, etc.). • Generate the right balance of "business and science" from early discovery through commercialization. • Identify key "open questions" that the team needs to answer . 	<ul style="list-style-type: none"> • Become stagnant – the world goes on, so you and your team better know where it's headed. • "Assume" without validating your assumptions – over and over again (when your assumptions change, so does the project plan!)

Putting It All Together



Get Your Team Committed to Outcomes.

- Develop the business case jointly so everyone buys into it: what's the promise, what's in it for them, and what's most important for success (set the key performance indicators upfront).
- Set up the right indicators and rigor for tracking project performance.
 - Regular project reviews (team, peer/expert, management, portfolio)
 - Ask tough questions in team meetings, and review risks and dependencies to prevent unnecessary surprises.
 - Use multiple indicators, not just schedule performance, to track and drive the right performance and corrective actions: i.e., requirements completion/changes, clinical success criteria, business case changes from gate to gate, launch performance indicators, etc.
- Tie team and individual performance to project success indicators.

Transform Heroic Acts to High Performance Behaviors.

- Perform a Project Health Check.
 - Holistic view of the project
 - Cross-functional team & stakeholder input
 - Get buy-in for an action plan for rapid improvement
- Complete lessons learned and post-launch reviews: integrate findings and actions into projects & organizational and process improvement plans – take improvement seriously!
- Look for root causes of issues:
 - Keep asking “why”...
 - Address issues and behaviors within the team and affecting the team.

Change Management Behaviors That Get in the Way.

- Be clear: what's working, what's not... what are the consequences?
- Engage your sponsor's support in dealing with management imperatives, political agendas and lack of prioritization.
- Manage expectations proactively:
 - Make sure that senior management is on board with the goals, business case, value drivers, risks and trade-offs. The "bad news" may be hard to hear, but better now than after the worst has already happened.
 - Make sure that your project plan delivers the business case.
 - Don't forget that your team members ARE the experts. Act like it in how you communicate (i.e. instead of posing problems, recommend solutions backed up with data).
- Think what's right for the business – not just the project.

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August 24, 1-2pm Eastern

Free Webinar: Global Pharmaceutical & Biotechnology R&D – Challenges, Opportunities, Pathways

Sept 14-16 and Oct 6

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Sept 28 (Kick-off), Tuesdays@12pm Eastern
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