

# Clinical Trial Supply Chain

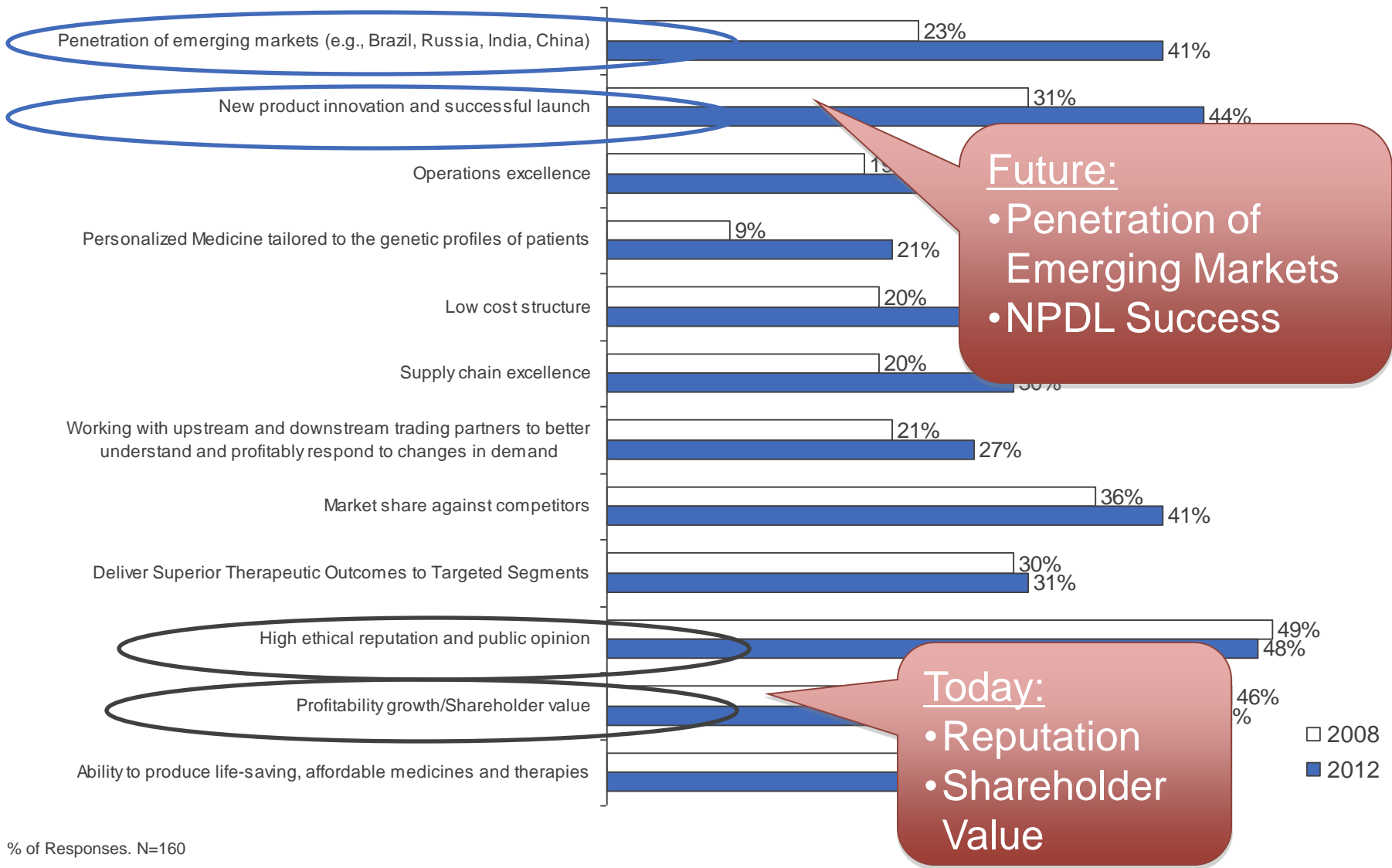
*Driving Transformation for Excellence*

October 20, 2009

# Key Success Criteria of Life Sciences Companies

Q84. What are your company's key success criteria in 2008? Success can relate to profitability, productivity and revenue growth etc.

Q85. What do you think will be your company's key success criteria in 2012? Success can relate to profitability, productivity and revenue growth etc.



% of Responses. N=160

# Summary of Key Findings

## What are the most significant CTSC challenge to date?

### • Expected Responses

- Roles & responsibilities not clear
- Getting the right kit at the right time to the site
- Disconnected application infrastructure
- Cost
- Risks inherent in a clinical supply stock out
- Regulatory compliance
- Cold Chain Management

### • Pleasant Surprises

- Lack of end-to-end visibility
- Moving to a more collaborative organizational environment
- Recruiting & retaining top tier managers proficient in supply chain strategy
- Lack of robust performance measurement

## What are the expected benefits of CTSC excellence?

- Improving new product launch
- Maximizing efficiencies in the clinical trials supply chain

# Current State of CTSC

- Companies looking for new products to fuel future growth; Need to accelerate time to market & drive down supply chain costs
  - Lack of end to end visibility
  - Lack of upstream and downstream orchestration
- Great Need for Supply Chain Talent
  - Recruiting and incentivizing people in silos
  - Roles and responsibilities are not well defined
- Supporting Technology Architecture is a Must
  - Heterogeneous landscape does not provide visibility or a platform to make decisions
- Metrics and Capabilities
  - Today's measures are focused on execution level outcomes
  - Need KPI's that help diagnose the health of CTSC's from a strategic level
- Results
  - Lack of robust CTSC demand management
  - Lack of CTSC performance management
  - High rate of change – internal talent and external service providers

# “New” CTSC Thinking - 3 “Sticky” Concepts

- Transforming push-driven supply chains into demand-driven networks
- “Outside-in” translation of clinical supply chain priorities from the point of drug/device consumption back that is synchronized with clinical supply with an “inside-out” excellence in execution
- Transforming clinical trial supply chains into end-to-end, value networks that differentiate competitors through joint value creation activities across the network

***Insight:*** Implementation of a C&OP process that's necessary to facilitate a demand driven transformation within the CTSC

# Additional Insights

- Only 34% of companies forecasted CT demand at least twice a month
- 36% of companies surveyed still did not conduct planning meetings to translate upstream demand into an actionable operational plan
- 47% of companies changed key service providers more than 2x's in the last 5 years
- 53% of companies used Microsoft Office or equivalent to manage their clinical trial supply chain processes
- Just 23% of companies stated that their current clinical trial supply chain process are extremely effective

# What Does Good Look Like?

- “Achieving **upstream and downstream visibility** is huge for us as everyone in the company must know what’s going on. We have developed SOPs and use a web-portal to stay informed”
- **“Improving compliance with patients taking the drugs is another big area of focus for our CTSC.”**
- “We are investing in **resources with better supply chain capabilities.**”
- “As a mature company we already have IT investments. We’re working on an **architecture** to leverage these IT investments and make sense of a patchwork of systems.”
- “We have employed **postponement strategies** in packing to make our CTSC more **responsive and agile.**”

# In the Context of “Clinical Operations Planning”

- Team Members = Clinical Operations, Clinical Supply, Medical Monitoring, Biostatistics, API & Pharm Mfg, QA/RA, IT, Sourcing, Manufacturing, Program Management
- Challenges to Overcome = lack of ...robust forecasting, shared goals/trust, communication processes, supply forecasts matched to demand forecasts, leadership support, dashboard reporting, supply chain education
- Solution = start planning supply at time of program and/or protocol development, bi-directional service level agreements, metrics/dashboards, Sr. Mgmt Champion, demand & supply forecasting, cascading set of COP review meetings from quarterly to weekly
- Organizational Barriers = resistance to change legacy systems and processes, lack of root cause analysis of issues (too reactionary), lack of collective understanding of the value associated with COP excellence

# Panel Discussion