

How Will Comparative Effectiveness Research Impact Medical Product Innovation?

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Two Mega-Trends are Driving Change in the Healthcare Industry

Increasing demand for patient-centered, value-based healthcare

Explosive growth in scientific/medical knowledge and new technologies

Increasing Demand for Healthcare

- Aging population
- Many areas of unmet medical needs
- Many major diseases affecting broad segments of population
- Early treatment/prevention-new market segments
- Rising GDP/urbanization in emerging markets
- Expanded healthcare coverage

Revolution in Biology and Technology Provides Opportunities for Healthcare Innovation and Value Creation



- Mechanism based, targeted therapies
- Regenerative medicine, biologics and cell therapy
- Genomics
- Nano-technology
- Microelectronics and wireless technology
- OR of the future: navigation, robotics, imaging
- Health information technology
- Neurostimulation and other e-stim
- Convergence of drugs, biologics, devices and diagnostics
- Personalized medicine

Increasingly Challenging Environment

- Threshold higher for showing value of innovation
- Intense global competition
- Patent challenges
- Pricing pressures
- Evolving regulatory requirements
- Heavy public scrutiny

All Stakeholders in Healthcare are Calling for More Evidence

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- Growing demand for evidence for approval and market access (FDA, payers, physicians, hospitals and patients)
- Demand for more rigorous study design with short and long term outcomes
- Increased scrutiny for breakthrough, premium priced products

What evidence is needed and when is it needed?

Needs of Stakeholders for Evidence Are Different

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Access

Utilization

Policy
Makers



Payers



Regulators



Clinical Service
Providers



Patients &
Caregivers



Industry must address the interests of all stakeholders

Evidence Suitable for Product Approval Often Does Not Answer Questions Important to Other Stakeholders

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- FDA and other regulatory authorities
 - Focus on safety, efficacy and quality
 - High scientific standards
- Patients, clinicians, hospitals, payers and health policy decision-makers
 - Focus on improving decision-making based on perceived value of different interventions

What is Value in Health Care?

Value addresses two main questions

To what extent does a medical *intervention* improve health outcomes in patients *relative to existing interventions*?

Is the incremental *benefit enough to justify associated costs*?

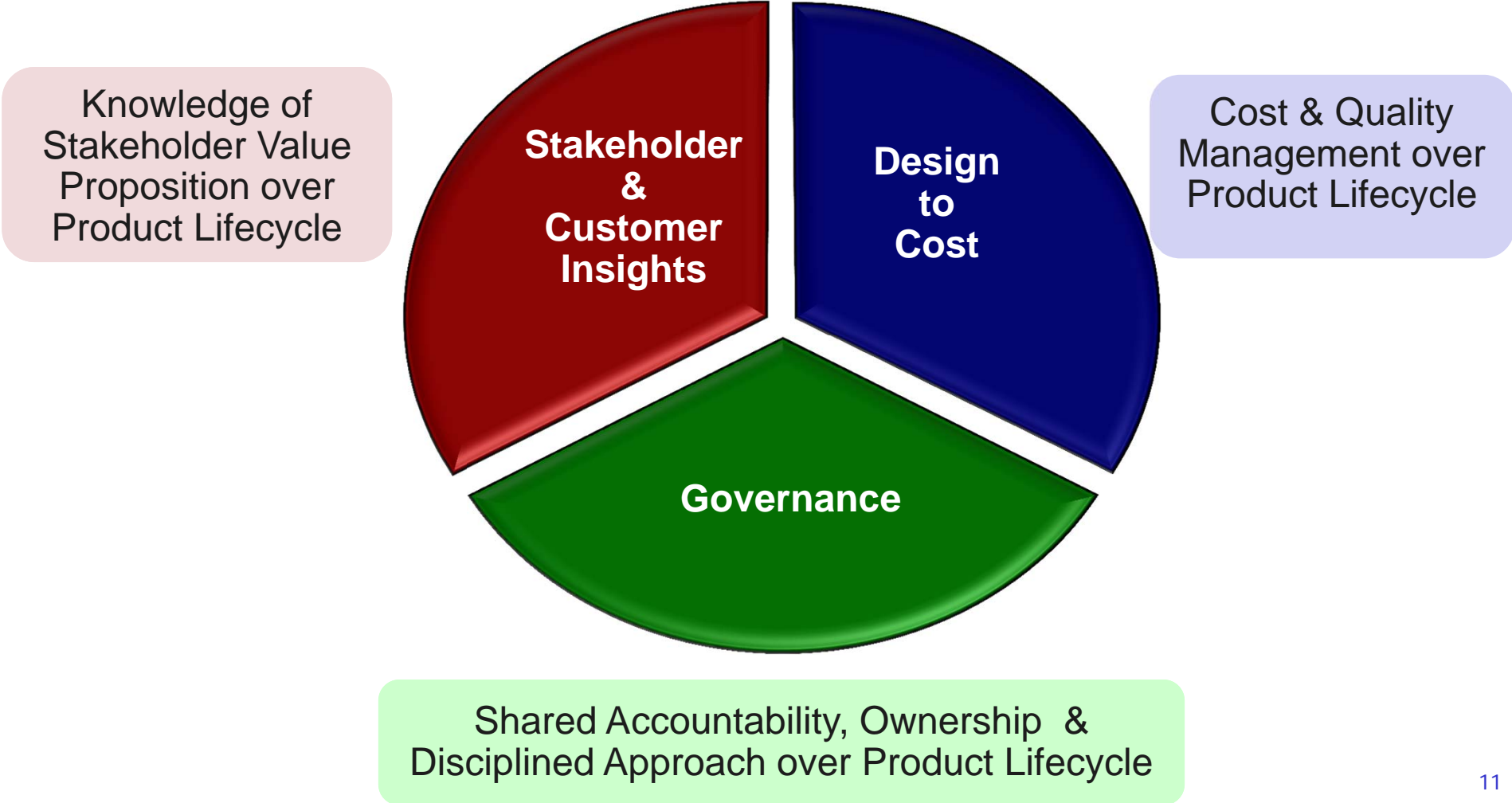
Design to Value

Understanding how to deliver value and quality to customers: patients, clinicians, regulators, payors and providers

Integrated approach that starts with customer/stakeholder insights, leading to design of products through an efficient development process and commercial model

Design to Value

DTV becomes a capability to create healthcare solutions with cost effective features that our customers value



Stakeholder & Customer Insights

Old Reality

- Price is not a key driver for purchase decisions.
- Customers value product features and performance over price
- Key stakeholders are clinicians
- Healthcare system has \$\$
- Consumers/patients input varies in decision making
- Evidence requirements are not high and have a short-term focus

New Reality

- Pressure to decrease healthcare expenditure
- Demand for increase in quality/safety/long-term outcomes
- Increased regulatory requirements
- Engaged consumers
- Increased price transparency
- Health technology assessment/comparative effectiveness
- Changing financial incentives, demographics

Define Unmet Healthcare Need in All Markets

Deliver on Target Product Profile: Cross-Functional Ownership

Create a Culture for Delivering Health Care Solutions

Stakeholder & Customer Insight

Define Unmet Healthcare Need in All Markets

- **Access stakeholder insights**
 - Investigate broad stakeholder base, stakeholder forums
 - Create knowledge banks and share best practices
- **Partner to create solutions “win, win”**
- **Analyzing competitive landscape**

Deliver on Target Product Profile: Cross-Functional Ownership

- **Rigorously develop a Target Product Profile**
- **Cross-functional project plan including process map**

Create a Culture for Delivering Health Care Solutions

- **Internal capability assessment**
- **Cross-functional ownership & accountability throughout the process**
- **Data-driven portfolio decision making**

Design to Cost

Old Reality

- Products are developed with primarily a clinician and patient focus
- Price & cost are often an outcome of the design process
- Ensuring payor acceptance of price is often considered late in the development cycle or after launch
- Cost management after launch is typically left to the supply chain functions

New Reality

- Products are developed with all customers and stakeholders in mind
- Price & cost are key design requirements
- Understanding what product aspects customers will pay for is included in the design process
- Cost management after launch is planned as part of the design through a multi-generation cost control plan

Gain a Deep Understanding of the Features & Functions that Customers Deem Valuable

Design to Cost (DTC) for the Product Lifecycle

Management of the Systems Cost of a Product: COGS, Service, Selling & Customer Usage

Design to Cost Summary

Gain a Deep Understanding of the Features & Functions that Customers Deem Valuable

- Provide resources to strengthen early customer insight to enable a better understanding of how customers value & trade off features and functions
- Make cost and quality required development targets for the design process

Design to Cost (DTC) for the Product Lifecycle

- Shared accountability by R&D, product supply & commercial for design to value goals & results
- Make feature/function tradeoff analysis a requirement
- Incorporate a Life Cycle Plan into the design process as a formal deliverable

Management of the Systems Cost of a Product: COGS, Service, Selling & Customer Usage

- Implement tools to better understand the Systems Cost Drivers of a new product offering. e.g. Activity Based Costing for complex products

Pipeline Governance and Lifecycle Management

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Old Reality

- **Focus is on Design, Development and Launch**
- Focus on core products with a 'launch, manage and react' approach
- **'Speed to Market'** dominates metrics
- Informal 'Discovery through Concept' Governance
- Business development/ R&D lead pipeline governance with varied levels of support
- **Not all functions involved** in all 3 processes or in trade-off discussions

New Reality

- **Balanced** product lifecycle and portfolio governance strategy
- Proactively address product pricing/value/design over time
- **Comprehensive metrics:** Customer, Design to Cost, Leadership
- More **formalized lifecycle process**
- Formalize cross functional team to lead lifecycle management
- Driven by Senior Management and **jointly owned by functional leadership**

Balanced Portfolio & Metrics

Invest in Enabling Process

Senior Leadership Ownership and Joint Functional Accountability

Governance Summary



Balanced Portfolio & Metrics

- Develop balanced metrics for both individual & families of products/solutions

Invest in Enabling Process

- Create processes that balance
 - Individual products & product families across their lifecycles
 - Portfolio of core & new to market solutions
- Formalize lifecycle management process & merge with development process

Senior Leadership Ownership and Joint Functional Accountability

- Visible senior leadership Ownership & joint functional group accountability throughout the product lifecycle
- Ensure successful change management & cultural alignment to support governance

Design to Value: Must Do's

Stakeholder & Customer Insights

- Define Unmet Healthcare Need in ALL Markets
- Deliver on Target Product Profile: Cross-Functional Ownership
- Create a Culture for Delivering Health Care Solutions

Design To Cost

- Gain a Deep Understanding of the Features & Functions that Customers Deem Valuable
- Design to Cost (DTC) for the Product Lifecycle
- Management of the Systems Cost of a Product: COGS, Service, Selling & Customer Usage

Governance

- Balanced Portfolio & Metrics
- Invest in Enabling Process
- Senior Leadership Ownership and Joint Functional Accountability

Getting to the right answer

- Need for the *right evidence*
 - RCT vs PCT vs observational
- For the *right question*
 - Safety & efficacy
 - Real world effectiveness & risk
 - Surrogate endpoints
 - Long term outcomes
- For the *right patient*
 - Genetics, preferences, comorbidities
- At the *right time*
- At the *right cost*
- For the *right answer*
 - Weighing evidence
 - Other policy considerations