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

- 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

Industry must address the interests of all stakeholders
Evidence Suitable for Product Approval Often Does Not Answer Questions Important to Other Stakeholders

- 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?

Note: Includes excerpts from the following sources:
- Sean D. Sullivan, PhD - An Evidence-Based Approach to Formulary Decision-Making: Part 1, Buenos Aires, Argentina, August 16, 2006
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.

- Knowledge of Stakeholder Value Proposition over Product Lifecycle
- Design to Cost
- Governance

- Stakeholder & Customer Insights
- Cost & Quality Management over Product Lifecycle

Shared Accountability, Ownership & Disciplined Approach over Product Lifecycle
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

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**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


- 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

### 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