

Risk Management Best Practice: Integrating Risk Management Strategies into All Phases of Product Life Cycle

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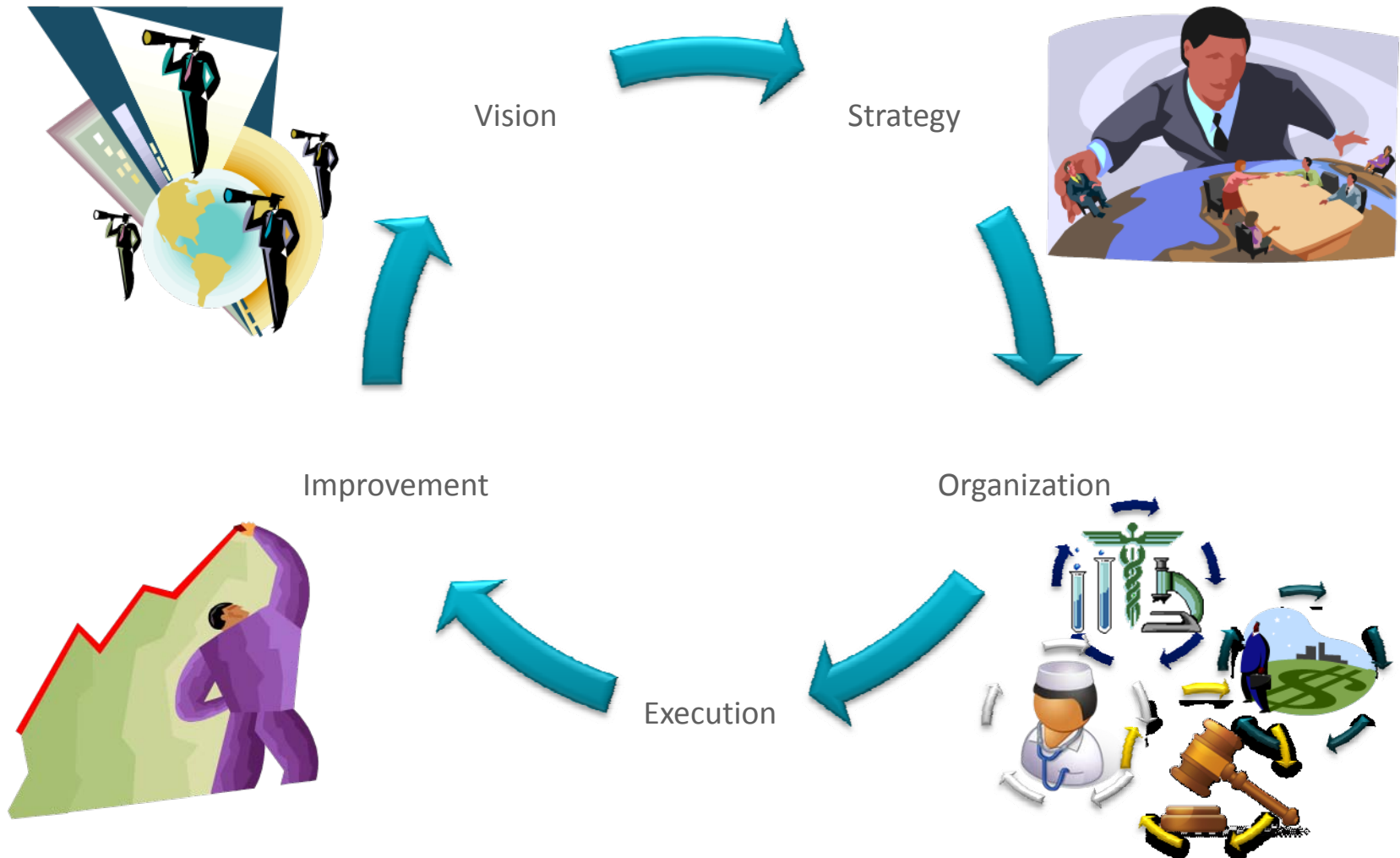
The Challenge



Critical Questions to Answer

- What's the Risk-Management strategy?
- How to operate an effective risk-management system
- How to objectively measure the trade-off between benefit and risk?
- When to conclude that risk outweighs benefit & who owns the decision?
- What is the impact of the benefit-risk balance on patients and ROI?
- What is the value (ROI and quality) of risk management activities?
- How to communicate risk?

Risk Management Continuum



RM Impacts the Entire Organization

- Benefit-Risk Management part of corporate strategy
- Alignment of stakeholders
- Creation of value
- Management of knowledge
- Technology
- Management of uncertainty
- Transparency & communication
- Organisational capabilities to be proactive, agile, adaptable, dynamic (responsive)
- Skills to deliver (non-core capabilities)
- Partnerships
- Communication

Competency-based View of RM

Management

- Corporate Lifecycle Oversight
- Principle of central accountability
- Cross-functional approach – stakeholder alignment
- Change management – manage change
- Advanced management skills
- Risk Communication
- Integration Science & Business

Medical-Scientific

- Integrated Lifecycle approach
- Knowledge finding and analysis
- Multi-disciplinary effective team-work
- Right methodology: Qualitative vs. quantitative methods
- Research design: clinical & post-marketing

Partnerships

- In-house, hybrid, outsourced vs. lifecycle partnerships
- Strategy and execution
- Facilitation
- Communication
- Best Practice



Product Lifecycle

How to Setup



Establish Governance Structure

Centrally enforced RM strategy matched to corporate strategy
Central Accountability of all stakeholders to senior management
(e.g. CMO, CSO, Head of Safety and Risk-Management)
Functional Alignment

Operational Core-Capabilities

Global processes, metrics, continuous improvement
Adaptability - Agility

Technology

Knowledge Management

People

Medical – Scientific, managerial
HR – skill assessment
Partnerships
Core-competencies

Integrated External Stakeholders

Patients & HCP
Regulatory Agencies

Training

Continuous education
Quality

Key Inputs

- The right structure and decision making process
 - Align and manage stakeholders – Accountabilities
 - Change management

Governance



- The right skills, beyond science
 - New Partnerships

People



- Making the machinery work ... and deliver

Process



- More important than ever – integrated safety and RM systems
 - Connectivity, integration, metrics, tracking, clinical DB, safety DB
 - Access to [safety] data
 - Surveillance & signal detection – signal maintenance
- Knowledge

Technology



- Pre-clinical, CT data, literature, spontaneous, epidemiological, signal detection

Knowledge



- Define and understand

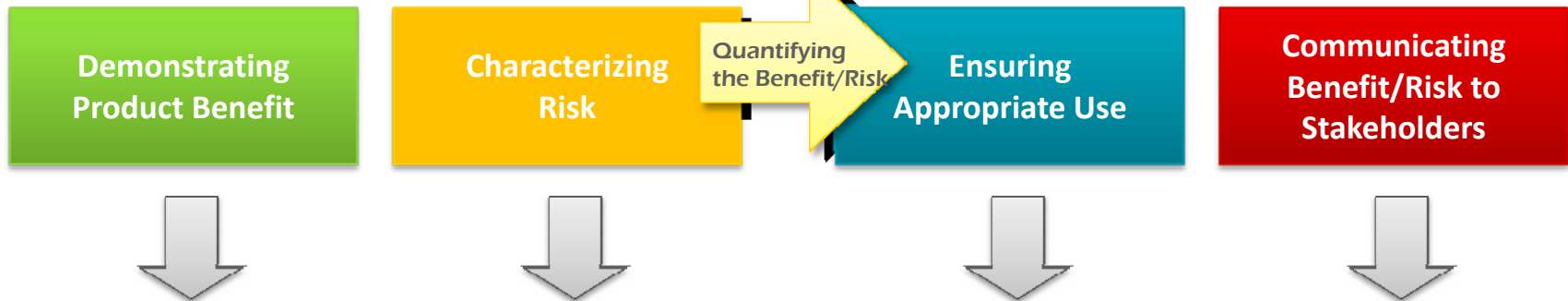
Risk Definition



Integrated Life Cycle Management of the Benefit-Risk Balance



Optimizing Your Product's Benefit-Risk Ratio



Shared vision, strategy and effective, efficient implementation are critical to achieving the most value from integrated PV and risk management activities.

Strategic Considerations to Support Lifecycle Safety and Risk Management



Create integration through shared vision and stakeholder collaboration

Stakeholders

Sr. Management R&D Strategic Consulting Risk Management Medical Affairs
 Marketing Pharm/Tox Pharmacovigilance Regulatory Surveillance Sciences Sales

Activities

Strategic Consulting

Functional Outsourcing

Efficacy Profiling

Risk Profiling

Benefit Profiling

Operational Safety and Risk Management

Alignment

Management

Opportunity

RMP Execution

Communication

Development Company

Healthcare Partner

Innovation, New Indications, Expansion

The Paradigm Has Changed !

- Effective Benefit-Risk Management is the combined output of all activities by all stakeholders of clinical development and commercialization
- Organizations need new skills, new ways to operate, new partnerships, and new visions to appreciate the complex changes mandated in the field of Risk Management

Thank You!



- Questions?

