

Extracting Maximum Value from your Quality System and Processes through Integrated Operations

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State of the Industry

- **Dynamic Drug Safety Environment**

- Shifting Public Opinion due to Negative Press
 - Withdrawals, Recalls, Cancelled Trials, Rare AEs, etc.
- Changing Expectations of Safety Operations
 - Regulators, Politicians, Shareholders, Patient Advocacy Groups, General Public
- Changing Regulatory Landscape
 - Differing Country Regulations despite Harmonization Efforts

- **Sluggish Drug Safety Response to Dynamic Environment**

- Minimal process and technology investments secondary to a non-revenue generating operation
- Legacy safety processes and tools have proven to be only marginally scalable to and consequently able to address the requirements of a continually changing safety environment

State of the Industry

- **External Issues**

- Health Care Practitioner Issues
 - Underreporting of Adverse Events
- Regulatory Authorities
 - Need to Update Processes, Tools, and Technologies
 - Need to Improve Organizational, and Financial Effectiveness

- **Internal Issues**

- Operations Management Issues (**Today's Focus**)
 - Process Inefficiency
 - Organizational Inefficiency
- Data Management Issues
 - Incompleteness and Poor Incoming Data
 - Limited Standards and Non-Integrated Information
- Risk Management Issues
 - Inconsistent and Delayed Decisions
 - Reactive Risk Management and Compliance Processes

State of the Industry

Operations Management Issues (Today's Focus)

- Process Inefficiency
 - Inconsistent and Non-Standardized Processes, Procedures, and Training
 - Cumbersome Processes with Redundant and / or Unnecessary Activities
 - Inefficient Process Handoffs / Stakeholder Interactions along Integration Points
 - Limited Transparency Across Processes
- Organizational Inefficiency
 - Limited Transparency Around Roles, Responsibilities, Accountabilities, and Ownership
 - Uncertainty Around Escalation Processes
 - Uncertainty Around Communication Processes
 - Metrics and Motivational / Reward Mechanisms not Linked Optimally to Process / Strategic Goals
 - Organizational Change Resistance

State of the Industry

Data Management Issues

- Incomplete/Poor Data, Due to:
 - Underreporting of Adverse Event Reports
 - Poor Incoming Data
 - Non-Standardized Safety Data Across Multiple Internal/External Systems with Differing Objectives
 - External Safety Data May Not Meet Needs or May Not Be in a Useable Form
- Inaccessible Data, Due to:
 - Limited Standards and Processes for Interoperability between systems
 - Internally Disjointed and Non-Integrated Information
 - Externally Disjointed and Non-Integrated Information

State of the Industry

Risk Management Issues

- Inconsistent Decisions, Due to:
 - Non-Standardized Risk Identification and Containment Processes
 - Non-Standardized Risk Assessment and Evaluation Measures
 - Non-Standardized Risk Mitigation Decision Processes
- Delayed and/or Uninformed Decisions, Due to:
 - Decision makers/stakeholders not clearly defined
 - Resistance to accountability and / or risk taking
 - Incomplete Information / Poor Data
 - No or inadequate Data Mining, Data Analytics, and Signal Detection Techniques
 - Reactive Risk Management and Compliance Processes

Point of View

- By not adapting to the current environment and making the organization agile enough to adapt to further changes, may compromise the ability of individual companies to mitigate key operational, strategic, regulatory, and reputation risks – risks that can give rise to the business and financial risks that pose a significant threat to stakeholder enterprise value.
- We believe that the industry may guard against exposure to excessive and unnecessary business and financial risk – and thereby protect stakeholder value – by thinking differently and enacting fundamental changes around traditional drug safety processes, practices, methods, approaches, and tools.
- Our recommendations around what steps companies can take to address the challenges of the current and developing pharmacovigilance environment fall into three general categories. We propose re-engineering the traditional concepts of the pharmacovigilance framework by utilizing forward-looking approaches in **integrated operations management, data management, and risk management** that borrow and leverage best practices from across the industry to create the foundation necessary for a best-in-class pharmacovigilance approach.

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About Hospira

- Hospira is a specialty pharmaceutical and medication delivery company launched from the core global hospital products business of Abbott Laboratories.
- Bringing proven leadership and a nearly 70-year track record of producing high-quality products, Hospira provides a breadth of technology solutions that help improve the safety and effectiveness of patient care.



The Business Need

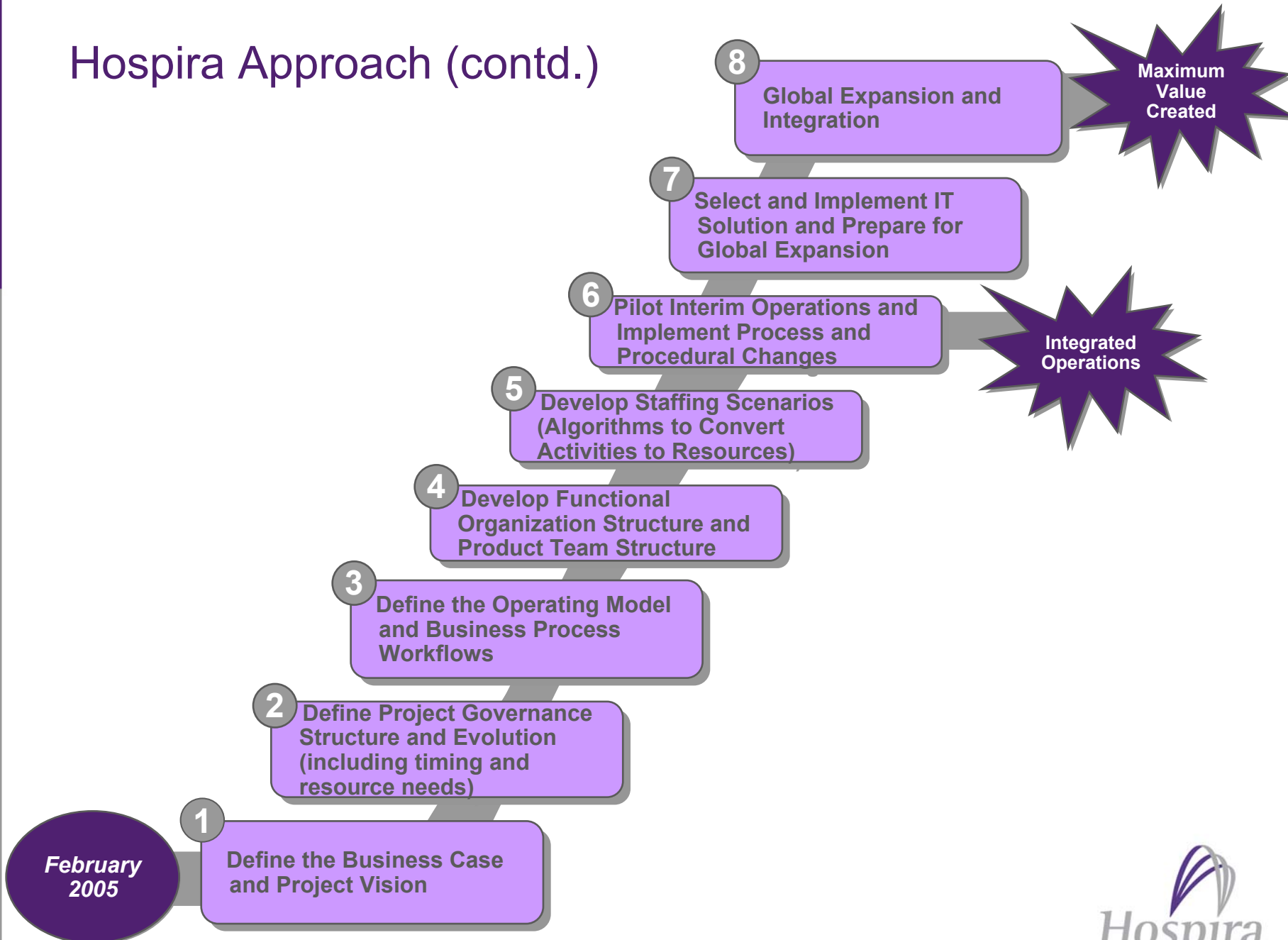
- In an effort to continue to provide quality in care to their clients' Hospira undertook a process of reviewing its existing complaint management processes, policies and procedures for both its drug and device products to:
 - Stay current with industry changes
 - Develop a scalable process and system
 - Standardize and centralize complaint management operations
 - Prepare for global expansion
 - Improve analysis of quality and safety metrics
 - Improve internal and external customer satisfaction

Hospira Approach

- The approach we took began with:
 - Partnering quality and safety personnel to scope out future global vision
 - Identifying and clarifying the processes and operating model
 - Identifying “as is” and “desired” state for the scalable environment
 - Assessing skill sets required to support “desired” state
 - Consulting and obtaining “buy in” from Hospira senior executives
- Identified and partnered with PwC’s Pharmaceutical Strategy Practice to assist Hospira in:
 - Verifying desired Operating and Functional Model
 - Developing process maps for each stage of the Operating Model
 - Initiating Process Narratives and Work Instructions
 - Developing realistic project timelines and “cut-over” plan
 - Providing external unbiased expert opinion throughout lifecycle of project



Hospira Approach (contd.)



ST and LT Objectives

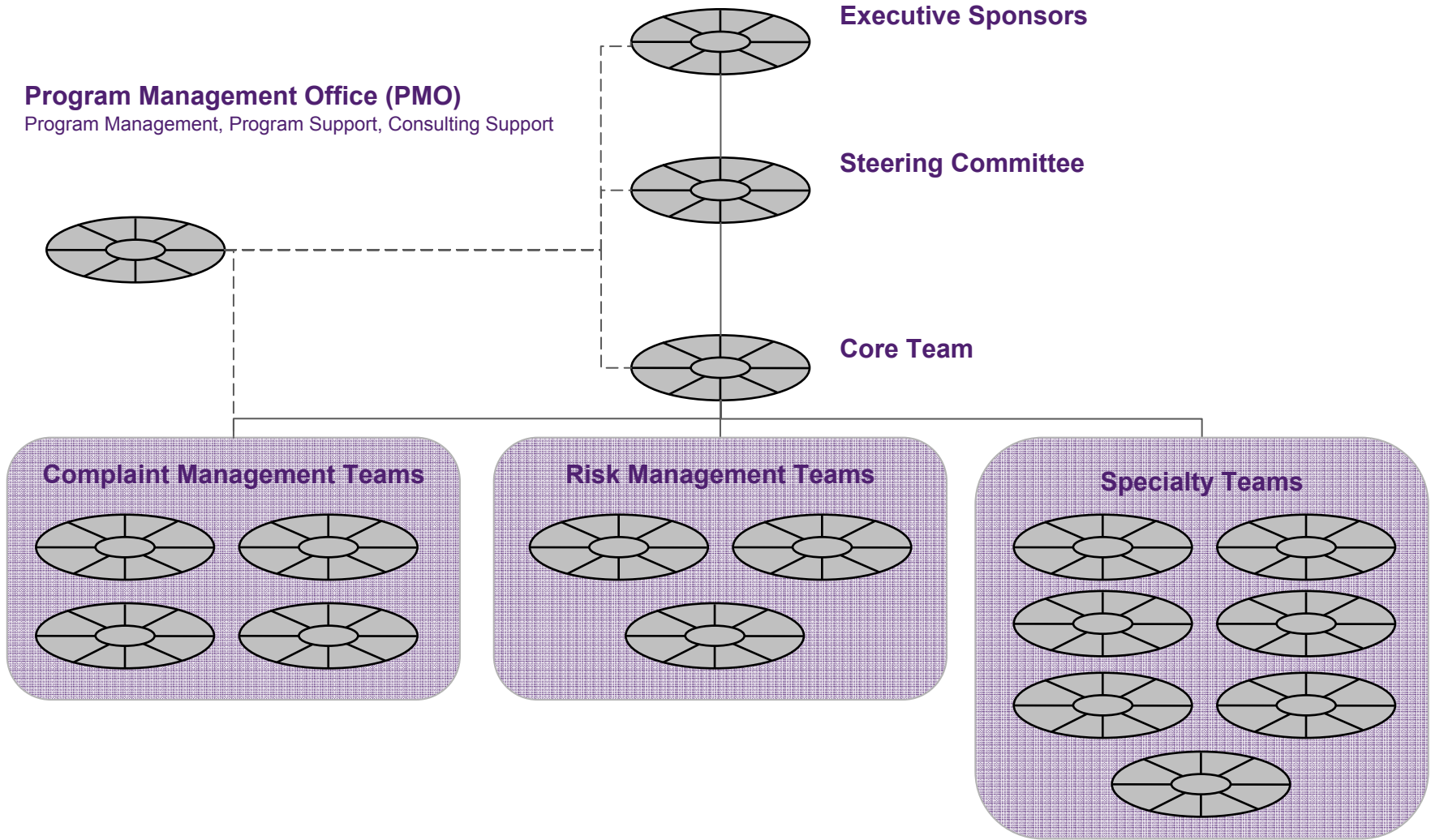
- **Short Term Objectives:**

- Develop standardization and centralization of process and operations
- Identify and correct inefficiencies and eliminate non-value added tasks
- Begin the process to improve internal and external customer satisfaction
- Prepare for global expansion

- **Long Term Objectives:**

- Develop streamlined and scalable process operation
- Develop proactive vs. reactive operations
- Increase customer satisfaction
- Improve financial fitness

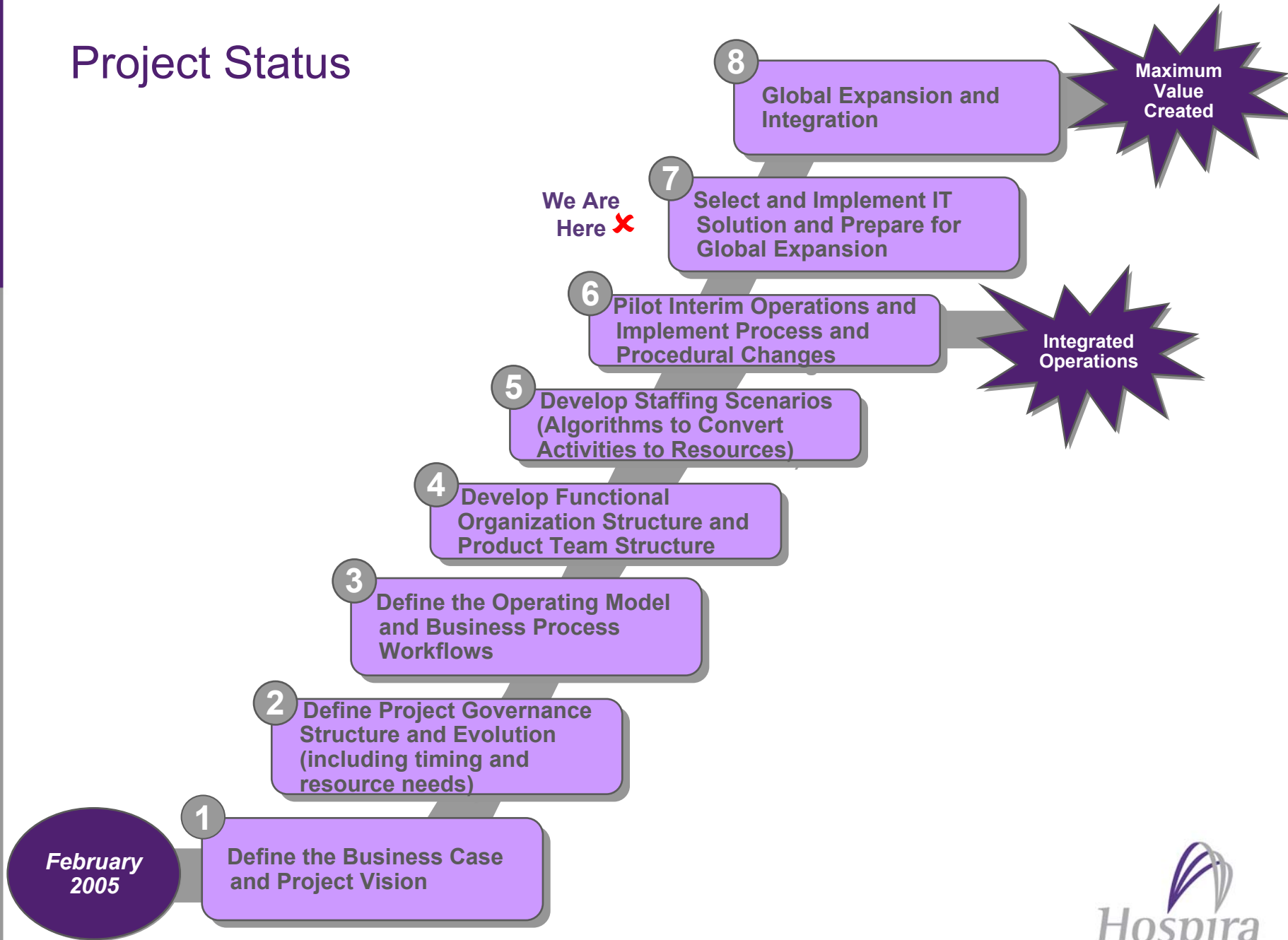
Project Governance Model Example



Implementation Challenges / Lessons Learned

- Ensure top-down organizational buy-in at key stages/milestones of the project
- Draft a business case with a clearly articulated business need and the ROI
- Identify/Map business processes prior to defining requirements
- Partner with outside expertise to facilitate identifying and implementing business process changes
- Clearly understand implications of choice at each stage of the project
- Determining the proper method to developing/changing process, culture and operating model
- Develop a realistic and staged system implementation plan/evolution map
- Ensure needs assessment is conducted on infrastructure (software systems, telephones, etc.) to support transition to "desired" state
- Do not underestimate the time, resources, or effort involved!!! Management needs to commit the internal and / or external resources (FTEs) required to complete project in a methodical and reasonable time frame.

Project Status



Thank You!

Q&A



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