

Twelfth Annual Pharmaceutical Regulatory and Compliance and Best Practices Forum

Pre-Conference II: Practical Approaches to Implementing an Aggregate Spend Program

Operational Challenges and Realities in Sunshine Readiness
Suj Patel, Director

November 2, 2011



YOUR MISSION | OUR SOLUTIONS

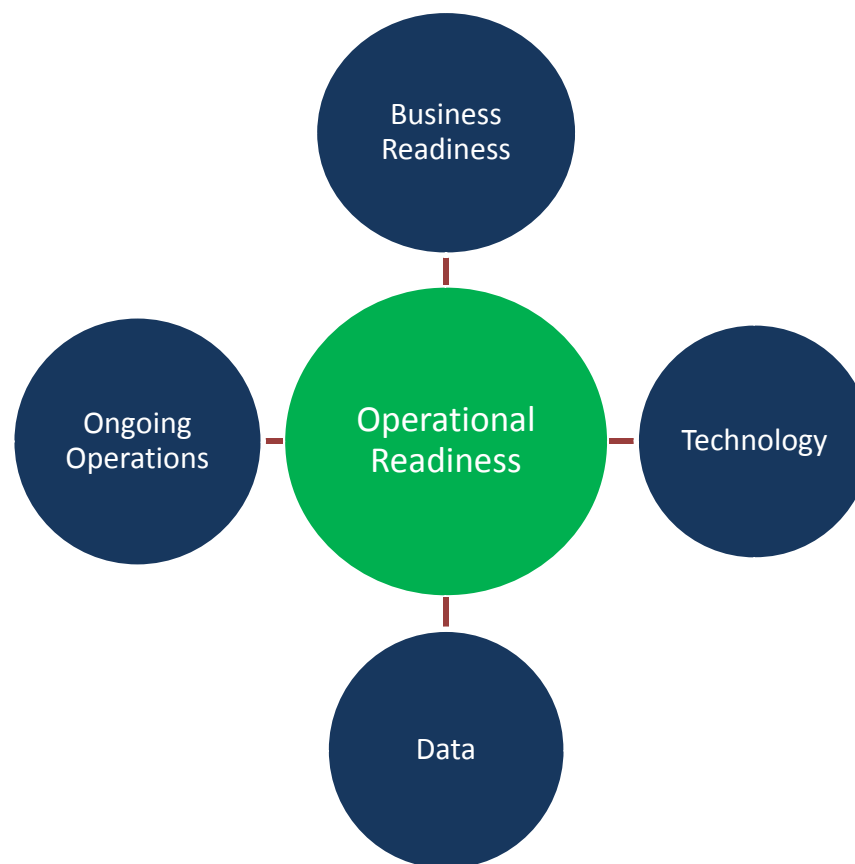
© Huron Consulting Group Inc. All Rights Reserved.

Huron is a management consulting firm and not a CPA firm, and does not provide attest services, audits, or other engagements in accordance with the AICPA's Statements on Auditing Standards.

Huron is not a law firm; it does not offer, and is not authorized to provide, legal advice or counseling in any jurisdiction.

Key Elements to Consider When Preparing for Operational Readiness

As organizations continue to prepare for Sunshine, four key areas of operational readiness need to be considered.

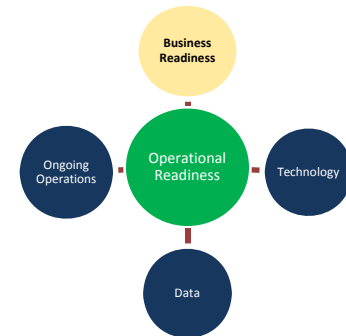


Business Readiness

Does your company have effective policies and procedures in place? Do they address pending Sunshine legislation? Have you trained your sales force?

Operational Challenges

- Planning based on known legislative guidance
- Re-defining policies and procedures leads to disruption to ongoing business processes (Change Management)
- Implement monitoring and auditing programs
- Educating HCP's
- Training Sales Force, Home Office, Business Partners



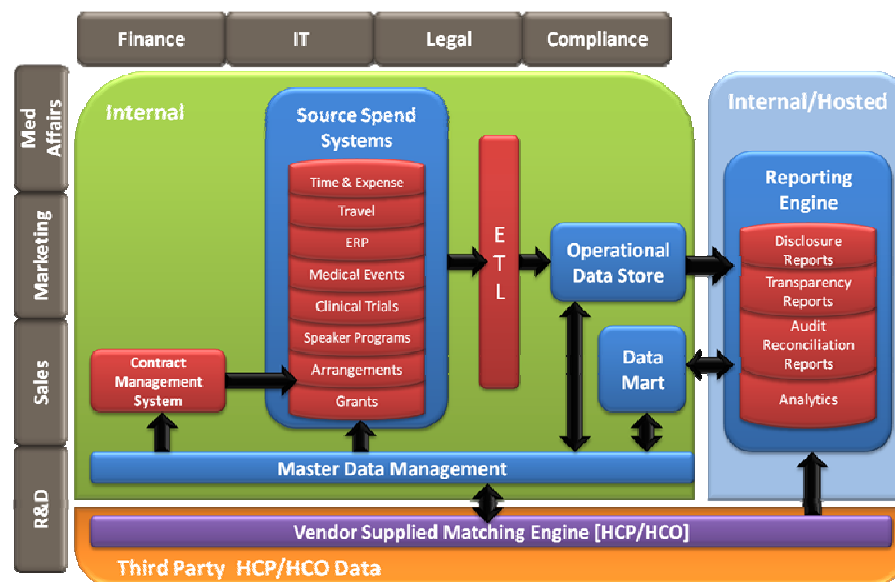
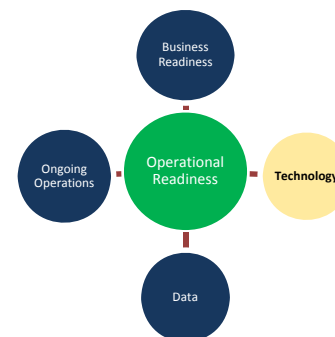
It is important to gain buy-in from appropriate level of management about the law now, so that they have time to determine whether and how to provide input into the rulemaking process. To make this decision, management must know the scope of the law and its potential impact on the business. They need to understand the short and long term implications of not only the public disclosure of the information, but also the breadth of information that must be collected, compiled, and reported.

Technology

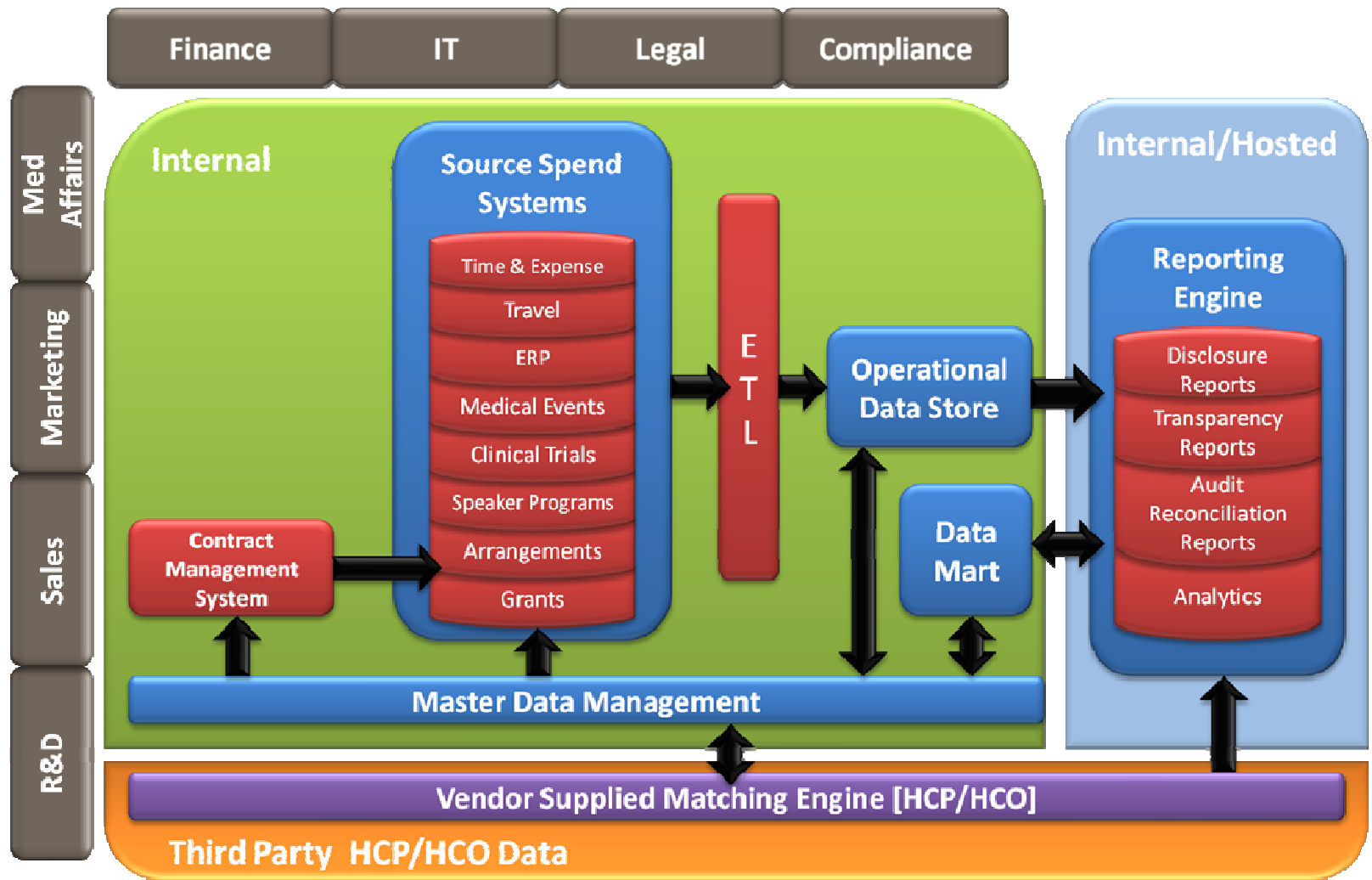
Does your company have systems, processes, and controls in place to capture and process critical data? Do you have projects in flight to continue integrating systems?

Operational Challenges

- Integrating your reporting solution with source systems and master data
- Modifying internal source systems to be able to capture the data
- Working with Third Parties to get the data in specific formats



Commonly Used Technical Landscape

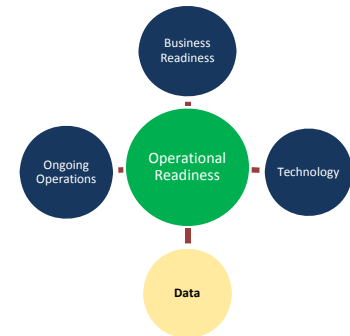


Data

**Is your company struggling to manage ongoing changes to data?
Do you have the people and processes in place to control the data
from data collection to data reporting?**

Operational Challenges

- Multiple spend sources contain disparate information and many times does not have sufficient details for reporting
- Multiple variations of a single recipient throughout various systems
- Data management, data governance and data stewardship processes are owned by multiple groups
- Ability for the solution to locate and cleanse duplicate entries without losing associations

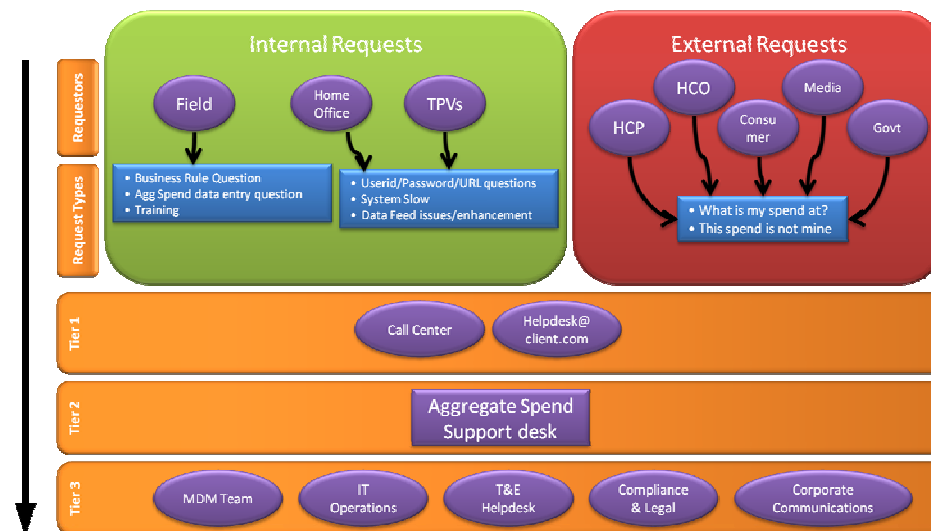


Ongoing Operations

Does your company have a support services platform today? Is it prepared to handle inquiries related to Sunshine? Is the support infrastructure set up for tracking and managing inquiries from inception to closure?

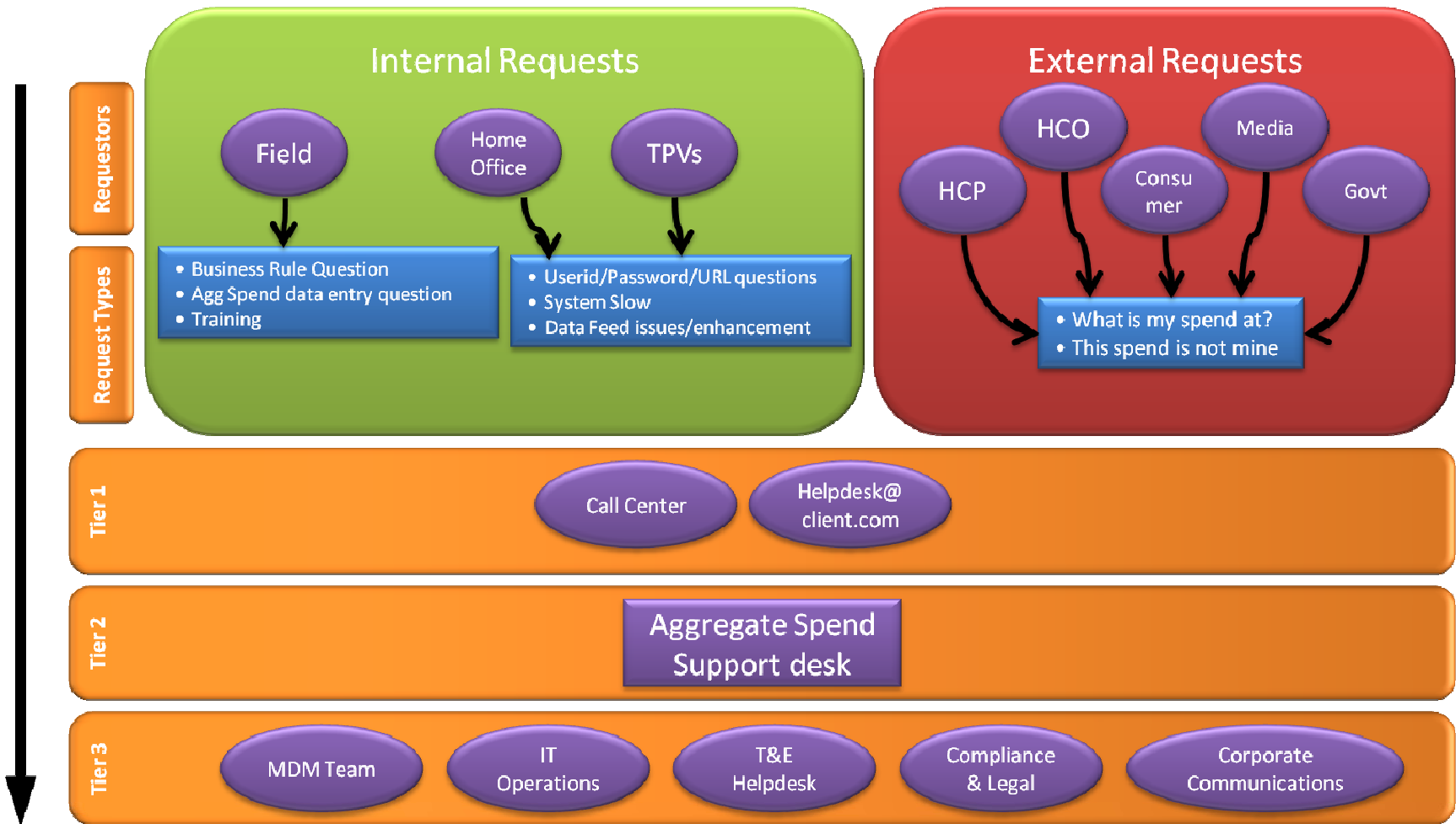
Operational Challenges

- Preparing and/or creating an infrastructure to manage Spend Inquiries
- Training call center personnel to handle Spend specific questions (at least train to be knowledgeable enough to escalate call)
- Establishing SLA's internally to respond back to customers in a timely manner



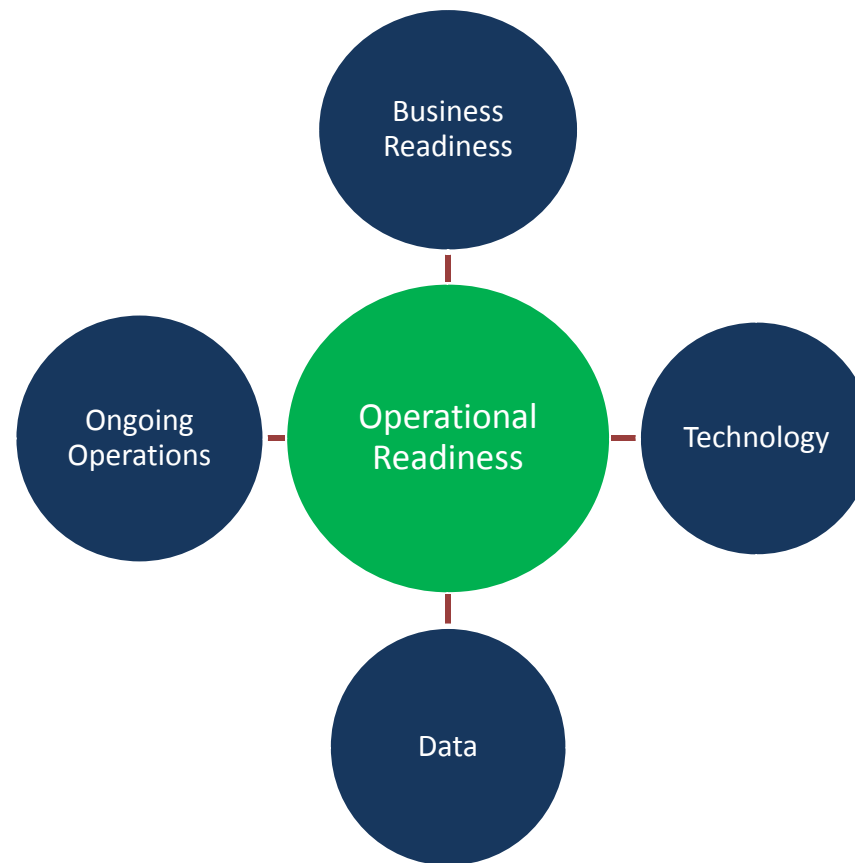
Field employees and representatives will face questions and demands concerning the risks that healthcare professionals face in the relationship, policy changes, and fears. Not only customer-facing employees, but also KOL consultants must be prepared to explain the interpretations, policies, and procedures put in place by the company.

Tiered Support Structure



Closing Remarks

Organizations are at varying levels of operational readiness. Effective communication and good business process will help you leverage technology to setup an infrastructure for your Aggregate Spend Program that will help you manage data, reporting, and ongoing operations across your enterprise as you continue to prepare for Sunshine Readiness.



HuronLife Sciences