

Applying Business Process Management (BPM) to Improve Aggregate Spend Reporting

March 2010

Changing Regulatory Landscape

Facing New Challenges

Pharmaceutical, Medical Device, Diagnostic, and Biotech manufacturers face ever-increasing pressures related to a changing regulatory landscape around Transparency and Aggregate Spend

Increasingly complex and changing regulatory landscape

- 8 states have existing disparate legislation setting limits on industry engagement and payments to customers and/or requiring the disclosure of these payments & costs
- More and more states will be passing distinct aggregate spend requirements
- Federal transparency legislation anticipated in Q1 2010
- Medical Schools & Institutions are enacting their own disclosure requirements/prohibitions
- Enhanced spend disclosure provisions in recent CIAs
- Voluntary corporate transparency and disclosure initiatives
- Other countries are developing transparency standards

Challenges - Operational

Customer Scope – diverse and growing list

Existing and emerging disclosure regulations are requiring disclosure of industry relationship and financial investments made to “**covered recipients**” that expand beyond the scope of healthcare practitioners (HCPs), thus requiring companies to capture profile information for **individuals, institutions**, as well as organizational hierarchy and **affiliation** information (HCP to HCP; HCP to HCO; HCO to HCO)

The effort to gather and align the data to individual customers becomes even more difficult as each department/business unit often has a separate profile established to identify the **HCP** and **institution**

- Healthcare Practitioners (HCPs)
- Physician Medical/Group Practices
- Consumer/Patient Groups
- Hospitals, Clinics, Nursing Homes
- Pharmacists/ Pharmacies/ PBMs
- Health Benefit Plan Administrators
- Medical Schools and Institutions
- Medical/Professional Organizations
- Government Officials
- Third-Parties

Challenges – Operational

Covered Recipient Interactions – many people internal & external to the organization interact with the same customers

The increased scope of transparency is causing companies to assess multiple points of interaction



Challenges - Operational

Spend Types - disparate internal & external information systems

The majority of the data that is required to be reported is either **manually captured**, is duplicated in **multiple systems** and needs to be reconciled, is **collected by a third-party** vendor, and/or is resident in **siloed** applications or data repositories across the organization

Payment types:

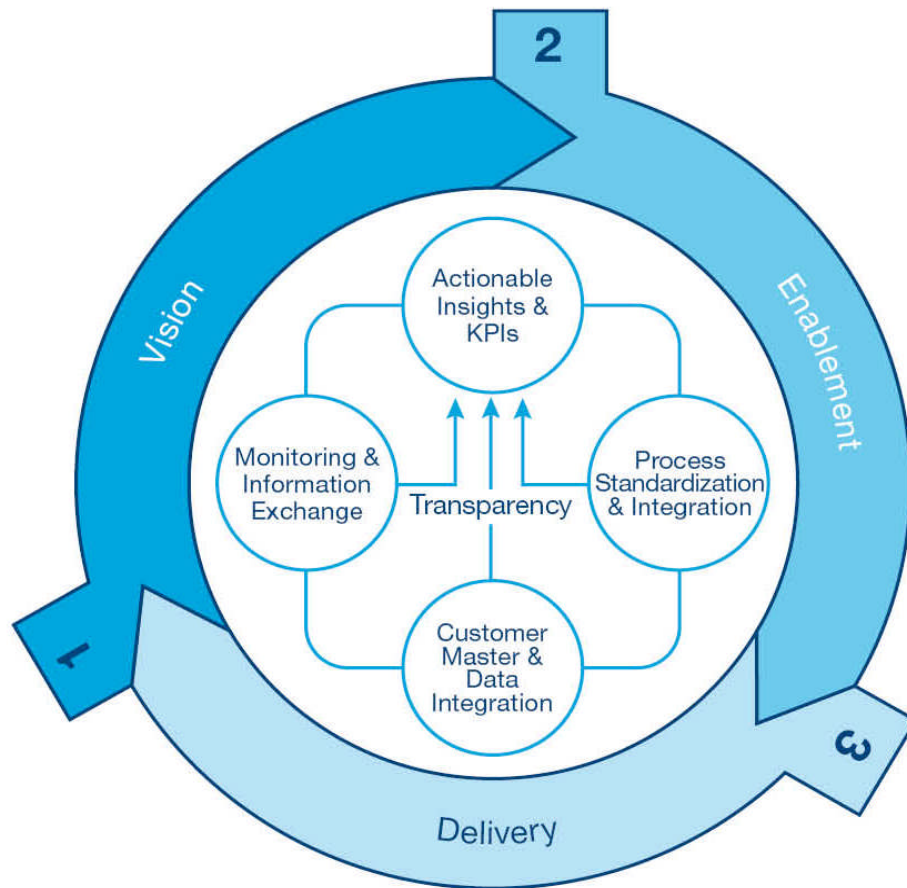
- Gifts (including text books and models)
- Meals
- Entertainment
- Honoraria and expenses associated with:
 - Speaker Programs
 - Speaker Training
 - Advisory Boards
 - Consulting Agreements
 - Investigator Meetings
 - Clinical Consulting
- Grants and Contributions
- Research payments (clinical trials, product development)
- Product sampling
- Advertising spend in state
- Aggregate employee/contractors costs associated with adv/promo activities
- Ownership or Investment Interests

Required data attributes reside in separate systems and contracts within:

- Sales
- Marketing
- Global Marketing
- Medical Affairs
- Contract Management
- Finance (including expense systems)
- Legal
- Compliance
- HR
- Research and Development
- Third-Party Vendors
- Contracted Agents & Alliance Partners
- Non-US Countries

PwC's Methodology

Our Approach for Aggregate Spend



1. Vision

Conduct a current state assessment to identify gaps and priorities. Develop a phased enterprise-wide vision and strategy for Transparency/Aggregate Spend

2. Enablement

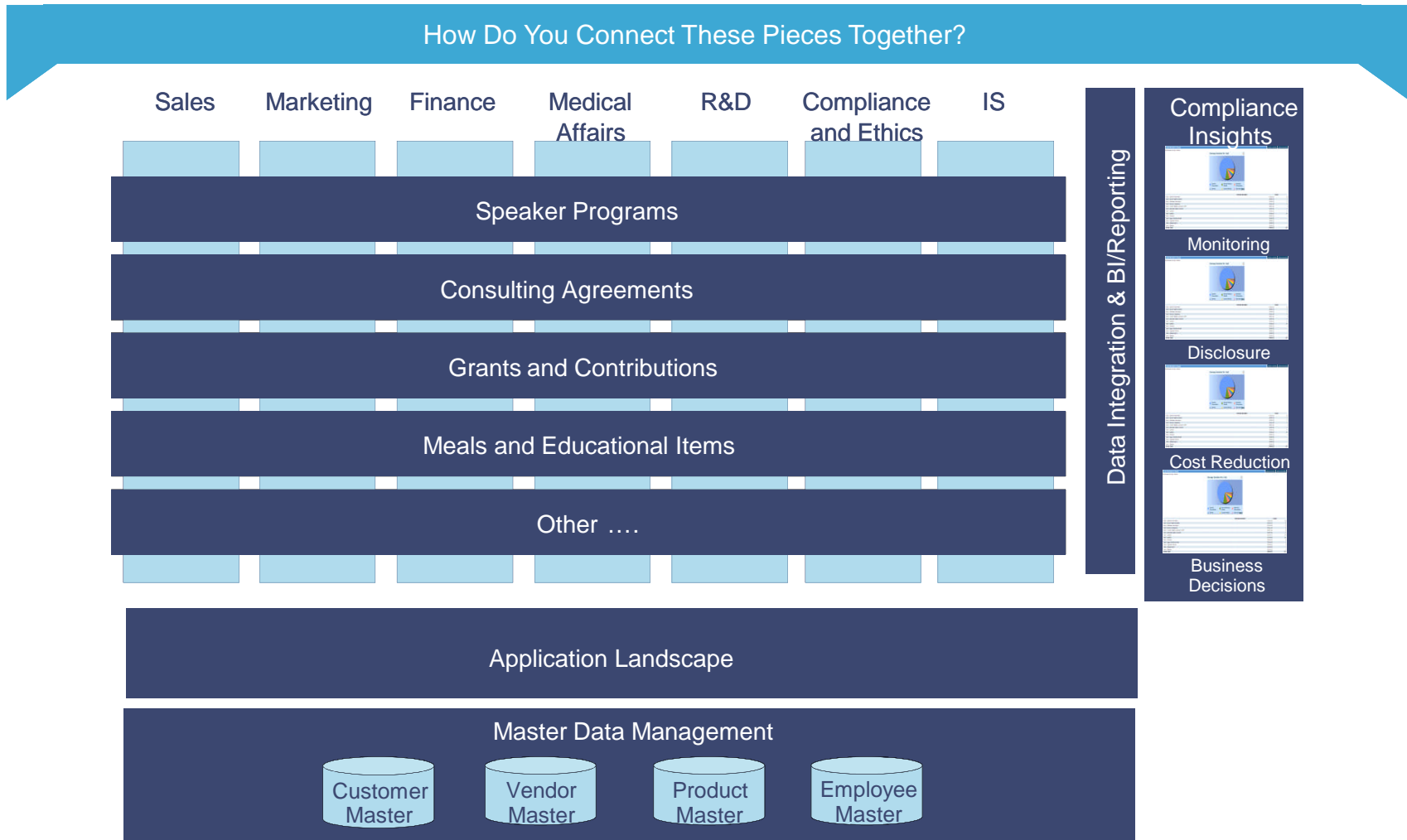
Enable an integrated view of spend by standardizing processes, establishing enterprise-wide master data management, consistently capturing spend at the point of engagement and implementing scalable/flexible solutions

3. Delivery

Deliver the ability to easily consolidate, analyze and proactively monitor aggregate spend and report internally and externally. Drive business value with actionable insights & metrics

PwC's Methodology

Developing Sustainable Solutions

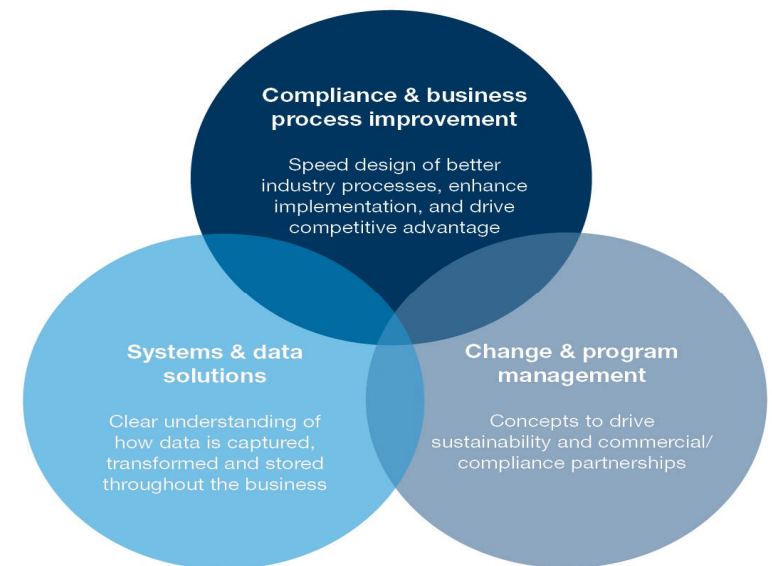


Current Landscape

Current state assessments uncover gaps in policies, processes, data, applications, change management and training

The current compliance landscape is largely fragmented and characterized by:

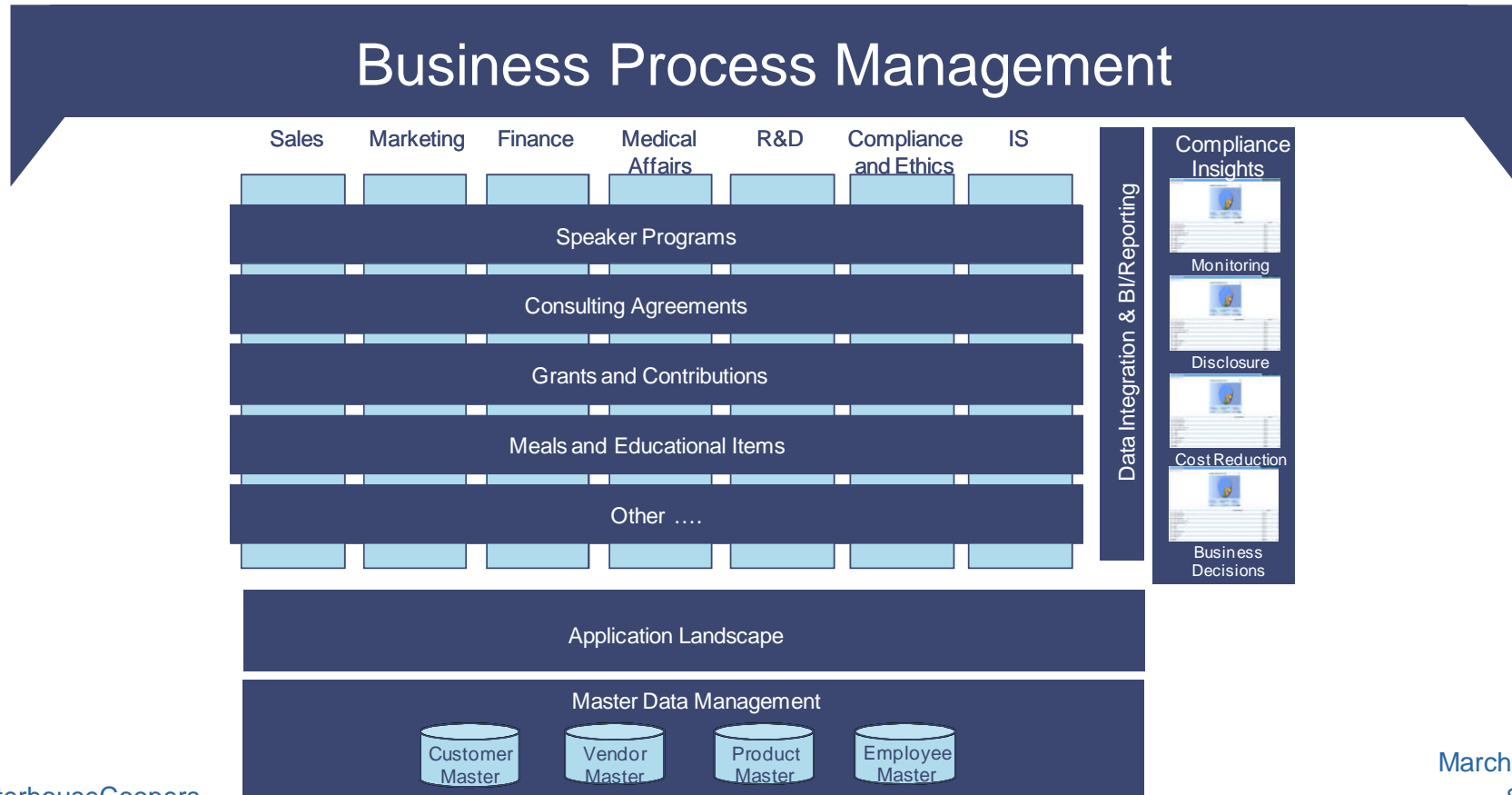
- Manual capture of customer interactions and spend
- Niche and legacy applications
- Inflexible systems that cannot expand or embed controls
- Non-standardized processes
- Inconsistent policies and spend limits/caps
- Disparate forms and contract templates, terms and conditions
- Multitude of third-party vendors
- Lack of data/system integration & reconciliation
- Geographic limitations



Future State

Business Process Management (BPM) as a building block

A BPM solution coupled with a BPM Center of Excellence (CoE) will help create an environment where integral systems function together to help create standardized and streamlined processes across business units and geographies so a company consistently captures accurate and complete records of their contractual arrangements and associated spend with healthcare professionals and institutions.

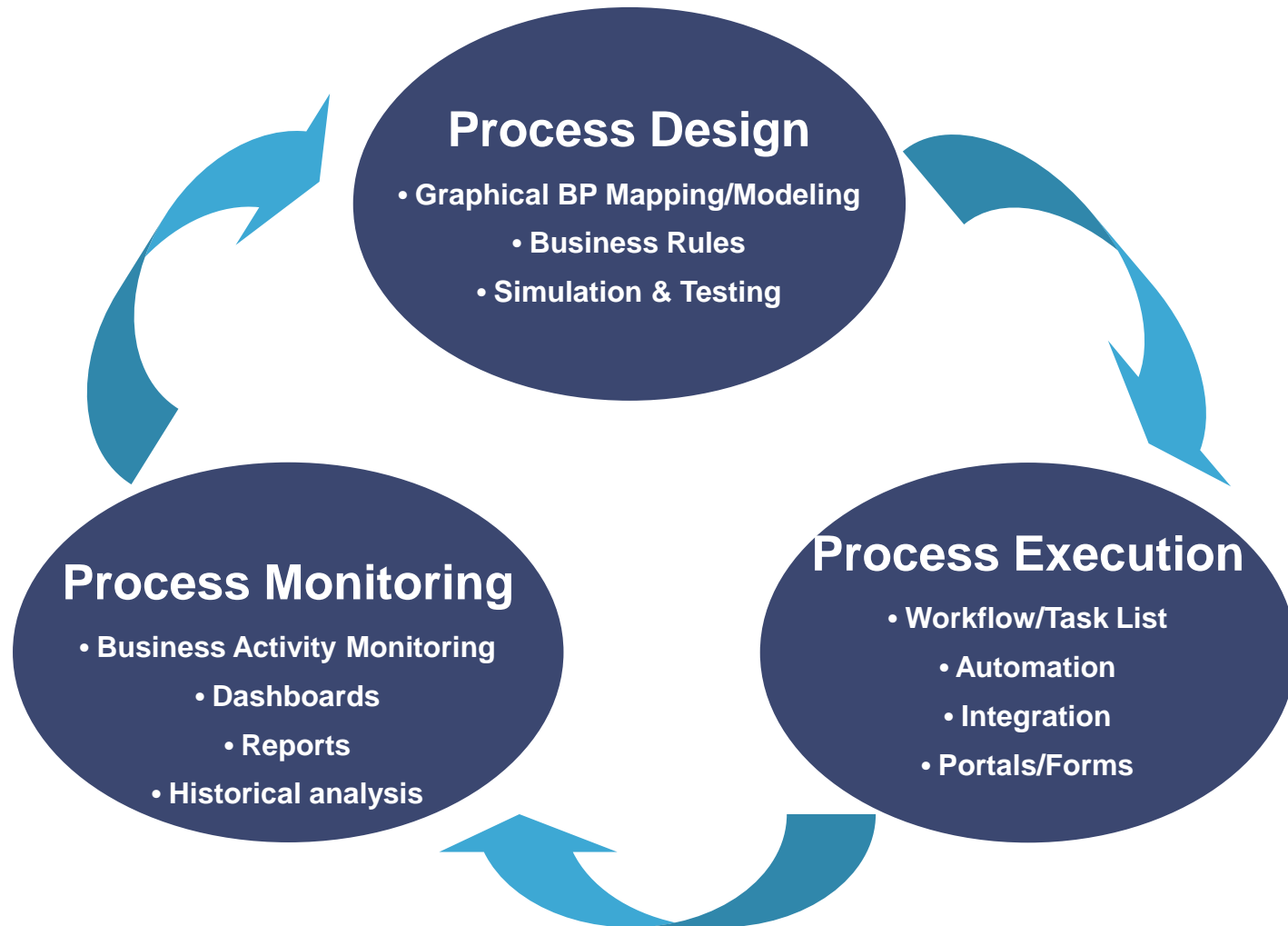


BPM Defined

What is Business Process Management (BPM)?

- BPM involves approaching business problems from a process-oriented perspective. This looks beyond system constraints and focuses on end-to-end process execution integration.
- BPM allows users across multiple organizations to interact with information and systems to manage workflows, hand-offs, and enforce consistent processes and business rules.
- BPM is software that enables orchestration or workflow between applications to support end-to-end processes and fills process and workflow IT gaps.
- BPM solutions provide the process execution engine needed to manage user workflows and integrate data into processes, while providing monitoring and reporting on process execution and performance.

BPM Functions



Industry Usage of BPM

Pharmaceutical and Life Sciences companies have begun to explore and implement Business Process Management software to automate and support a variety of compliance and non-compliance processes that require a lot of manual activity, multiple hand-offs across organizational groups, and interactions with various applications, including:

- Grant Processing (e.g. requests, approvals, rejections, and tracking)
- Fee-for-Service processes (e.g. Advisory Boards, Consulting Agreements, Speaker Programs)
- Aggregate Spend - creation, review, approval of aggregate spend and state disclosure reports
- Compliance Documentation Creation, Approval and Retention
- FCPA Monitoring
- Clinical Trial Initiation
- Incentive Compensation Reports & Payment processing
- Field Laptop Imaging

BPM to Improve Aggregate Spend

A logical first step is to leverage BPM as a cross-functional technology option to further mitigate risk, enhance compliance controls, and provide process monitoring across similar end-to-end spend processes

Spend Types

- Advisory Boards (Scientific & Commercial)
- Speaker Programs
- Speaker Training
- Consulting Agreements (Commercial, R&D, Managed Care)
- Grants, Sponsorships & IME
- Displays/Exhibits

End-to-End Process

- Initiating Request Forms
- HCP/HCI selection & exclusion checks
- Required reviews, approvals, and escalation
- Fair Market Value Assessment
- Contracting process
- Proof-of-performance & associated payment
- Payment Reconciliation (budget to actuals, contract terms to payment, within policies and caps)
- Document Retention
- Ongoing Monitoring & Auditing of process, vendors, and total spend

BPM in support of Aggregate Spend

Electronic Forms

General Information | Agenda | Location | Attendee Information

Attendee General Information

Number of Participants:

Justification for expected number of Participants:

Primary area of speciality of Attendees:

Target attendee Type:

Consultant Speaker Fee:

Total additional estimated compensation per attendee:

Is any attendee a Government Employee?

Route for Reviews & Approvals

By Work in Progress

| Agency | ID | Subject | Created by | Created On |
|--------|-------|------------------------|-------------------------------------|--------------------------|
| 20 | SP-10 | Events Approval - Meet | Anthony Leonard (Meeting Organizer) | Sep 18, 2008 12:22:12 AM |
| 20 | SP-11 | Events Approval - Meet | | |
| 20 | SP-15 | Events Approval - Meet | | |
| 20 | SP-18 | Events Approval - Meet | | |
| 20 | SP-15 | Events Approval - Meet | | |
| 20 | SP-16 | Events Approval - Meet | | |
| 20 | SP-19 | Events Approval - Meet | | |

Customer Lookup

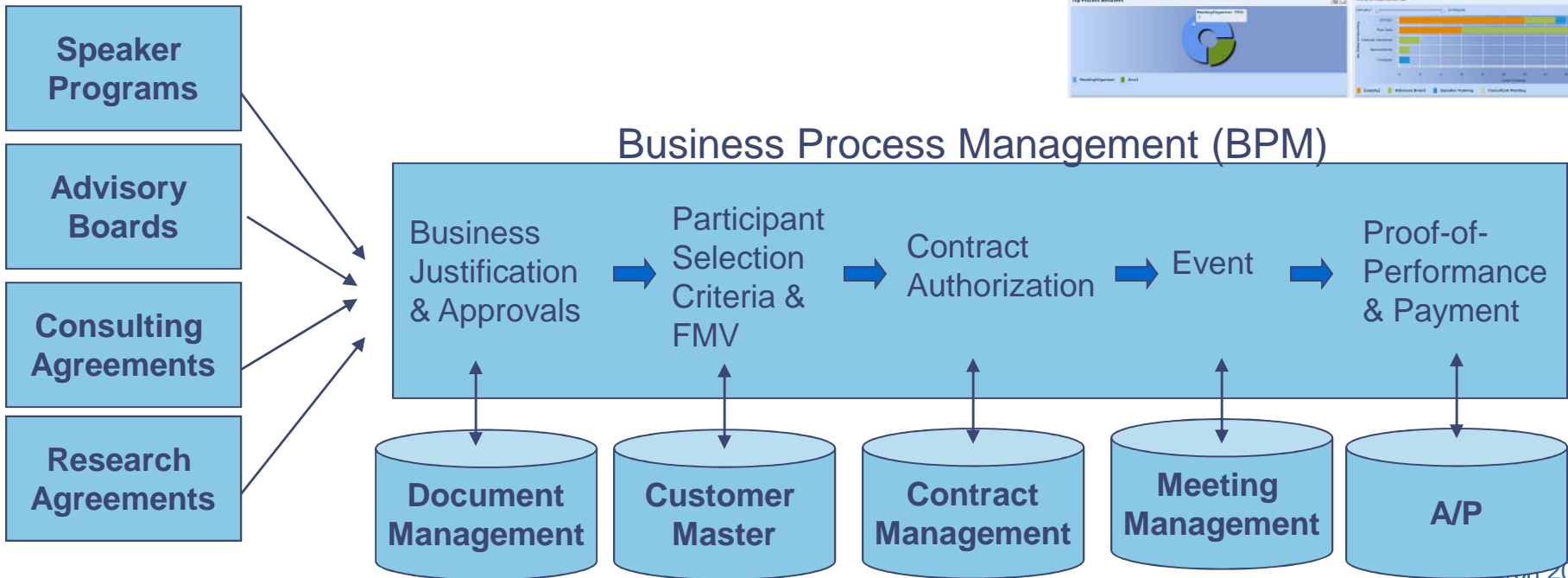
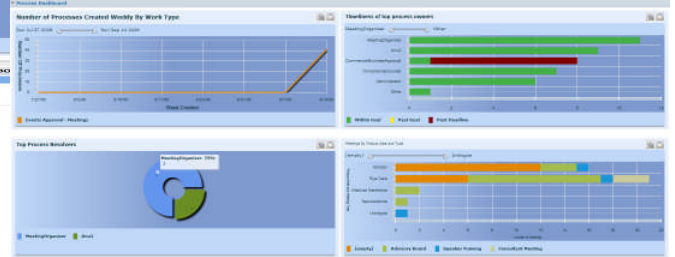
| First Name | Last Name | Medical Specialty |
|------------|-----------|-------------------|
| Ann | Shoale | Neurology |
| Ann | Shoale | Neurology |

Total Spend To Date: \$214,000.00

Attendee List

| ID | COL | FIRST NAME | LAST NAME | DESIGNATION | STATE | CONTACT METHOD | COMMENTS | ON BO |
|-------|-----|------------|-----------|-------------|-------|----------------|----------|-------|
| 53333 | | ANN | SHOALE | DO | VA | Phone | | |
| 44444 | | ANN | SHOALE | DO | VA | Phone | | |
| 22222 | | ANN | SHOALE | DO | VA | Phone | | |

Process Monitoring



In view of Aggregate Spend challenges, what are the benefits of BPM?

- Streamline, standardize, and align policies, procedures, and business process across Sales, Marketing, Global Marketing, R&D, and Third-Party Vendors
- Ability to get out in front of activities and review/approve them before commitments or made, money is spent, risks are incurred or activities are completed
- Manage the compliance environment by implementing automated workflow, stronger controls, and enforced business rules for customer facing processes
- Capture the type, nature and amount of spend related to each covered recipient engaged for state/federal reporting, monitoring, and to provide business intelligence back to the business
- Establish a clear consistent strategy defining how, when and where data is captured, integrated, and reconciled
- Integrate with enterprise-wide applications (T&E, A/P) and master data management repositories
- Incorporate governance, privacy & security considerations
- Eliminate the majority of manual activities and paperwork and establish an audit trail, greatly reducing the risk of human error
- Speed the approval of business activities and increase transparency and visibility into customer interactions

In view of Aggregate Spend challenges, what are the benefits of BPM?

BPM solutions are used enterprise-wide, thus providing additional benefit from a cost perspective:

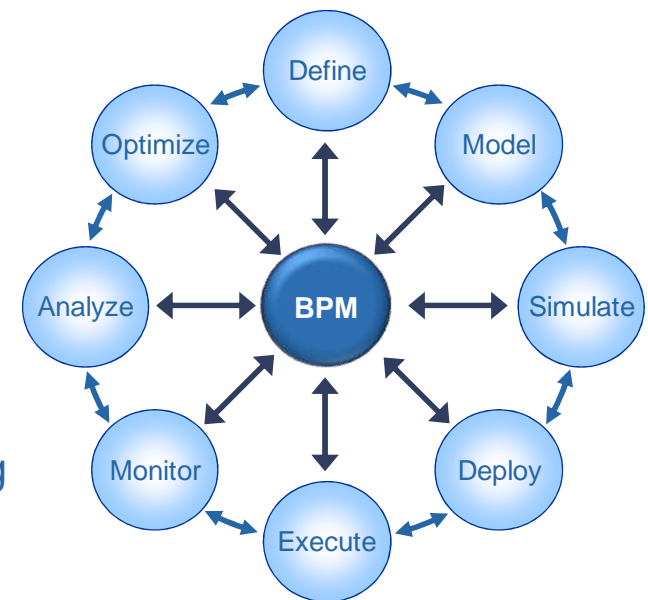
- Can apply same infrastructure to multiple processes
- Further support process standardization and integration
- Centralized management of business rules
- Apply data quality standards consistently across multiple processes
- Reduces software and hardware costs
- Reduces training costs
- Reduces development & maintenance costs
- Reduces overall Total Cost of Ownership (TCO)

BPM Center of Excellence (CoE)

Institute a sustaining business operations model

A COE establishes a centralized organization to:

- Facilitate continuous process improvement through the establishment, distribution, and enforcement of disciplined, repeatable, and standardized processes, tools, and templates for business process engineering (BPE)
- Proactively analyze and design future enterprise-wide core business processes for transparency or other business process improvement related opportunities
- Provide internal consulting to business units, application delivery teams, project stakeholders and sponsors regarding BPM and BPE practices and standards
- Measure and monitor performance across the organization and provide visibility into the health of BPM/BPE programs and projects
- Enable synergies with other established Centers of Excellence



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