# *Practical Steps Toward Complying with Sunshine Requirements*

## *Pharmaceutical Compliance Forum*
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**pwc**

# *Agenda*

The need

The approach

# *The need*

# *Business processes*

## Business processes meet specific objectives

Today's business processes have evolved out of the necessity to execute the initial business needs of a particular group or business unit within an organization. Many times, groups or business units operate in isolation causing similar business objectives to be met through very different processes, which produces disparate information.

Aggregate spend business processes cut across the business processes found in isolated groups and business units. Aggregate spend creates its own set of business objectives that may not be in alignment with the core spend processes, impacting the approach to efficiently and effectively capture and report spend across the organization.

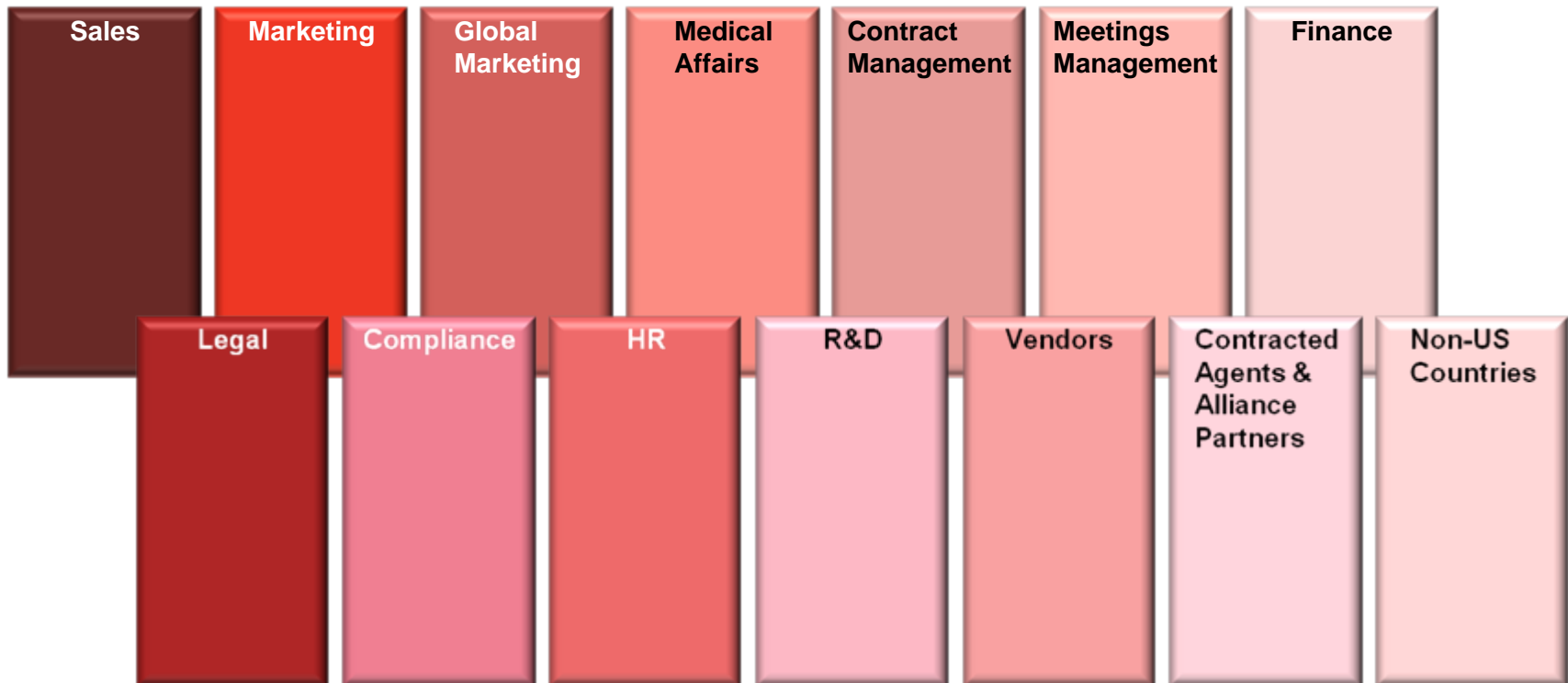# *Business processes*

## Resulting in the need to

- Establishing new aggregate spend business processes

- Standardizing and aligning spend processes across the organization

- Enabling aggregate spend business process through software solutions

# *Functional business units*

**Siloed business units use separate processes and disparate systems**

| Sales | Marketing | Global Marketing | Medical Affairs | Contract Management | Meetings Management | Finance |
|---|---|---|---|---|---|---|

| Legal | Compliance | HR | R&D | Vendors | Contracted Agents & Alliance Partners | Non-US Countries |
|---|---|---|---|---|---|---|

# *Process interaction participants*

**Linked by email, Separated by systems**



| Marketing | Legal | Compliance | Meetings Management | Finance | Vendors |
|---|---|---|---|---|---|

**Business Process**

| Information Systems | Information Systems | Information Systems | Information Systems | Information Systems | Information Systems |
|---|---|---|---|---|---|
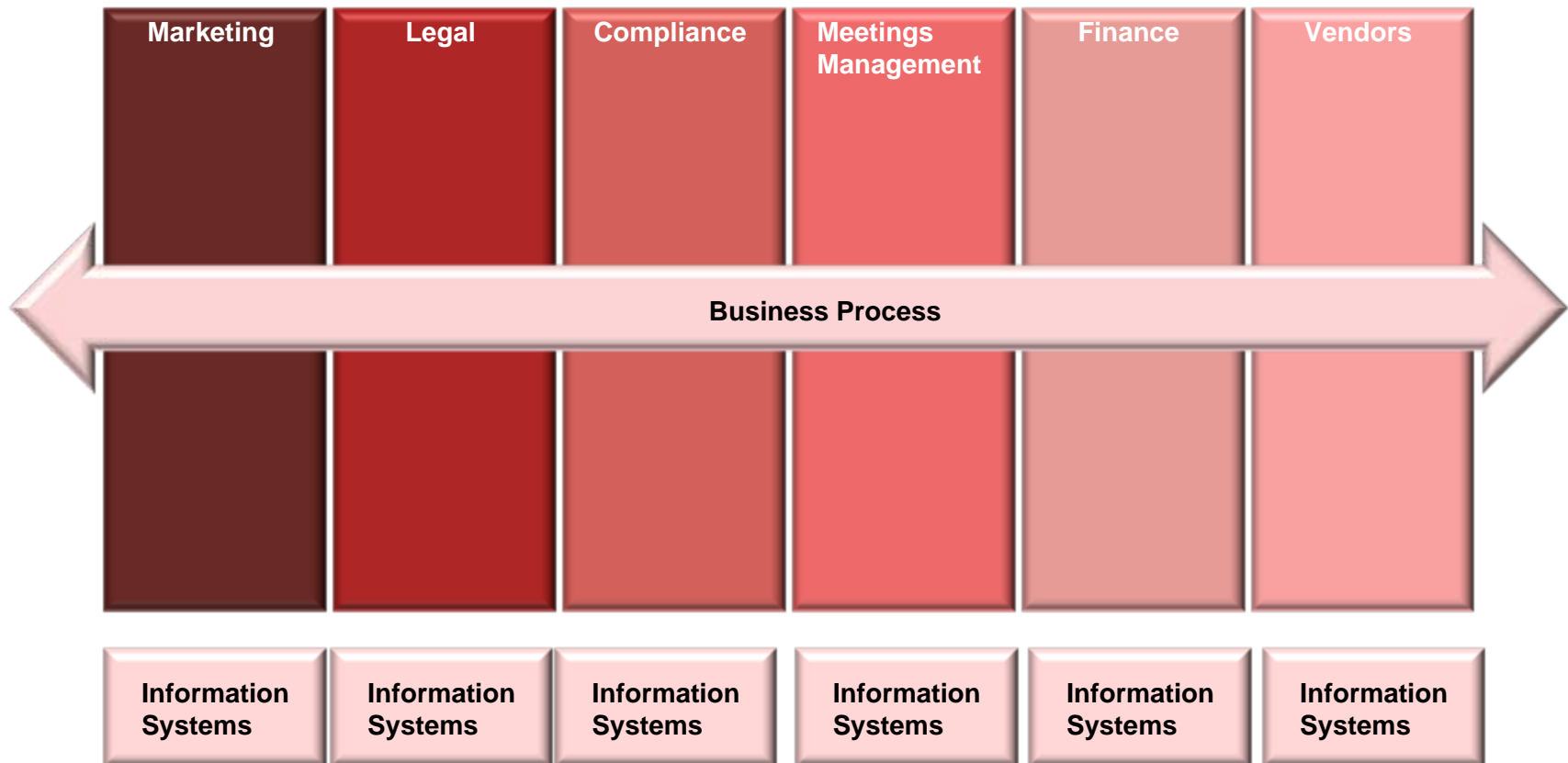
# *Core spend business process*

## Modifications required to capture needed level of detail

**Aggregate Spend Business Process**

| Speaker Programs | Activity and Budget Planning | Approval | Activity Execution | Tracking | Reporting |

| Advisory Boards | Activity and Budget Planning | Approval | Activity Execution | Tracking | Reporting |

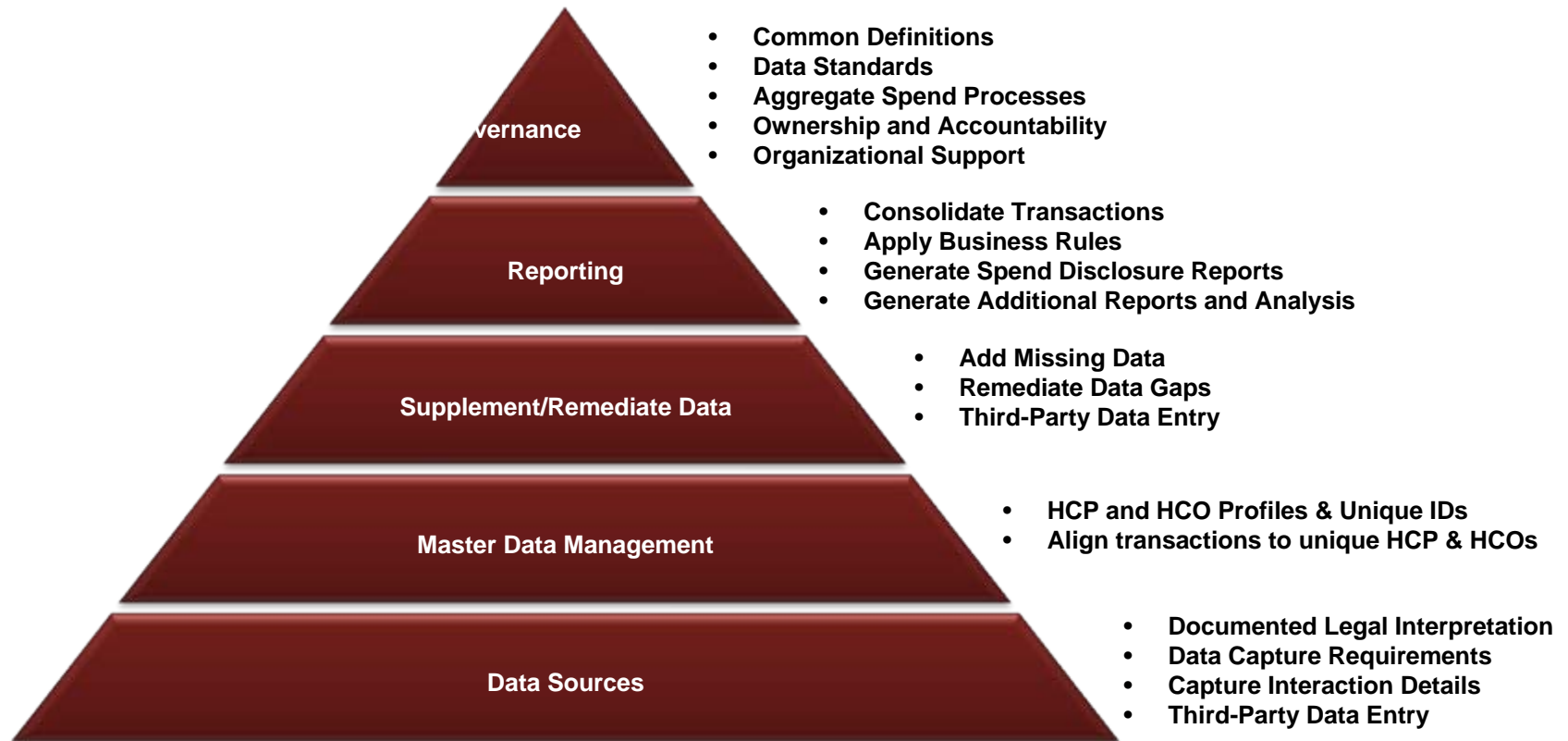| Consulting | Activity and Budget Planning | Approval | Activity Execution | Tracking | Reporting |
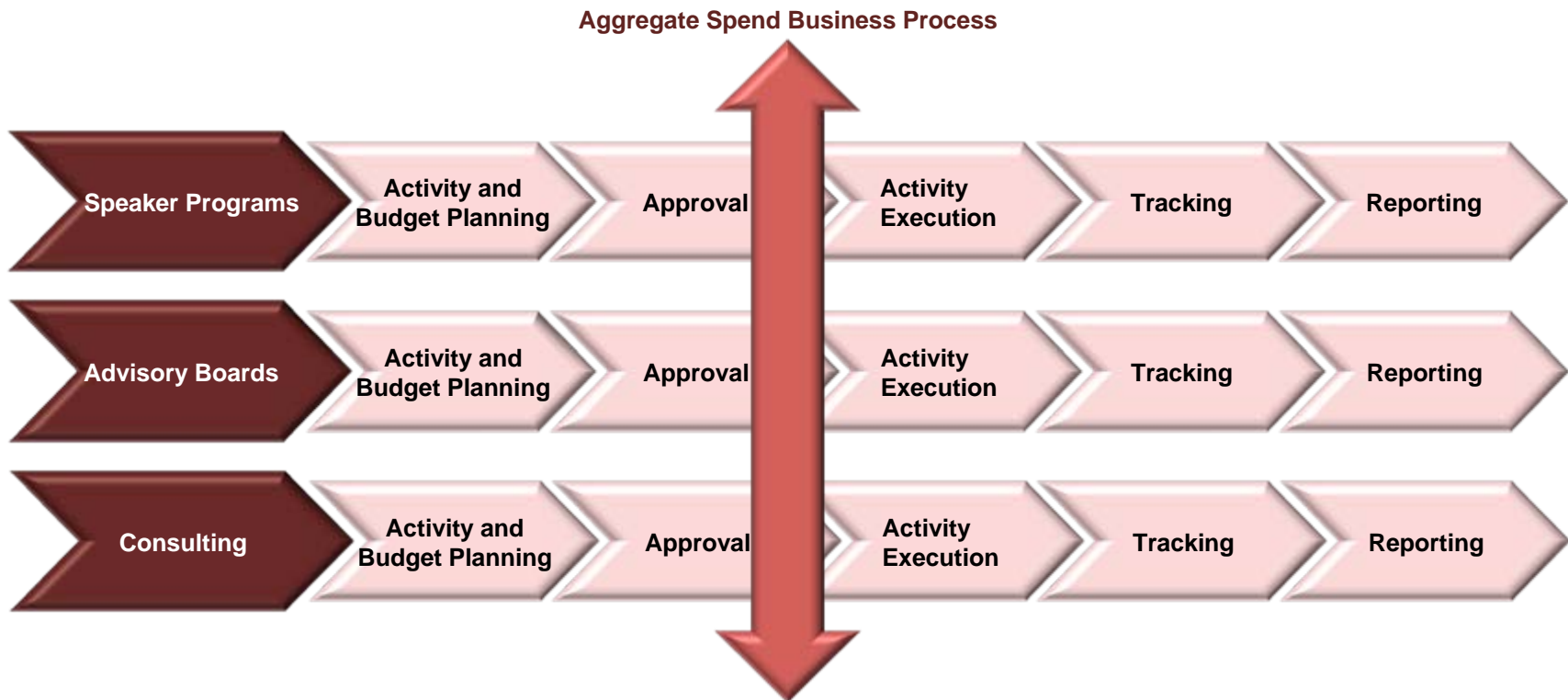
# *Complete HCP Spend Management*

**Companies are starting to take a complete HCP Spend Management approach from the initiation of an activity and budget planning through reporting to enable consistency and compliance through the entirety of the business process**

| Business Process | Activity and Budget Planning | Approval | Activity Execution | Tracking | Reporting |
|---|---|---|---|---|---|

**As-Is Reporting**

**Complete Tracking**

**Full HCP Spend Management**
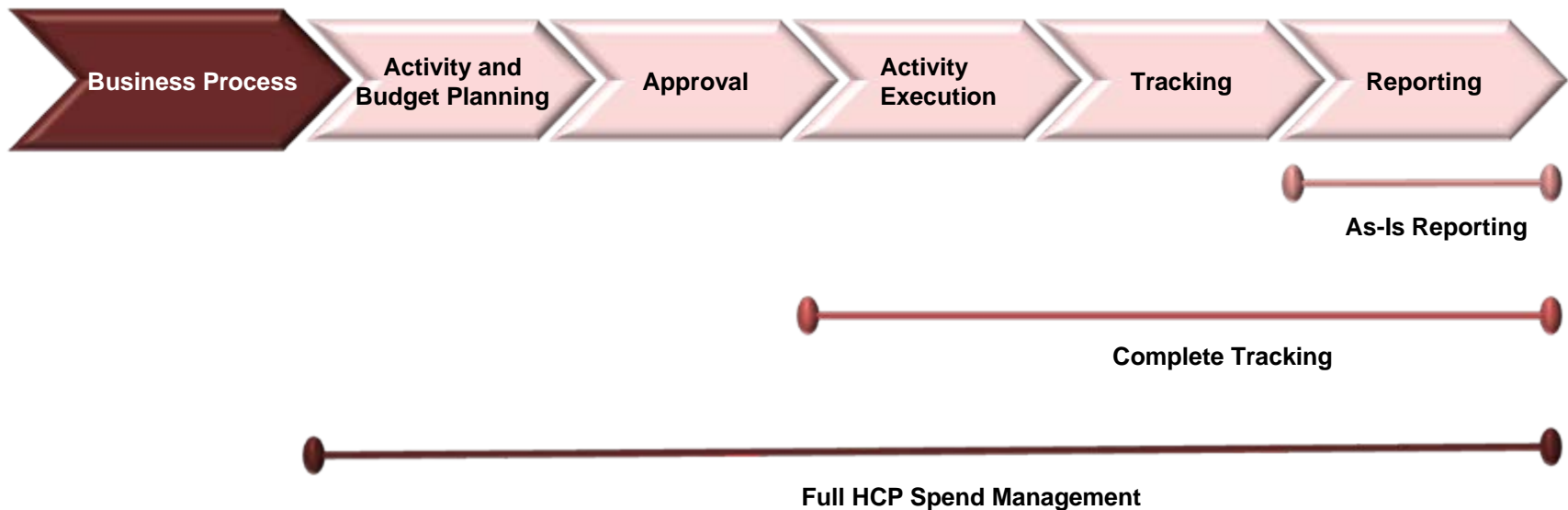
# *The approach*

# *Aggregate spend solution components*

**The following areas represent the solution components that need to be addressed as part of the Aggregate Spend future state design**



**Governance**
- Common Definitions
- Data Standards
- Aggregate Spend Processes
- Ownership and Accountability
- Organizational Support

**Reporting**
- Consolidate Transactions
- Apply Business Rules
- Generate Spend Disclosure Reports
- Generate Additional Reports and Analysis

**Supplement/Remediate Data**
- Add Missing Data
- Remediate Data Gaps
- Third-Party Data Entry

**Master Data Management**
- HCP and HCO Profiles & Unique IDs
- Align transactions to unique HCP & HCOs

**Data Sources**
- Documented Legal Interpretation
- Data Capture Requirements
- Capture Interaction Details
- Third-Party Data Entry

# *Data Sources*

**Focus on improving transactional data entry in source systems to capture data as accurately and completely as possible at the point of interaction and/or spend commitment**

- Modification of source systems

    - Modify source systems to capture additional data attributes

        ◦ Event/Interaction details (i.e., who, where, when)
        ◦ Payment details
        ◦ Process details (i.e., business justification, proof of payment)
        ◦ Associated Product(s)
        ◦ IDs to link Event, Covered Recipient, Associated Spend

    - Structure data entry for greater consistency and capture of details (e.g., list of values, required fields, data validation)

    - Expand use of systems to other divisions (e.g., tech footprint consolidation)

    - Streamline/Standardize processes and embed controls

- Typical Sources Impacted - T&E, ERP A/P, CRM/SFA, CTMS, Grants, Vendors

- Design processes/procedures to capture data for areas where up-front solutions not readily available or feasible

- Implement data standards & governance (i.e., gathering, validation & error/exception handling)

# *Master Data Management*

**Alignment of transactional data to existing master data elements (Customer, Product Masters, etc) to attribute spend transactions to unique HCPs and Institutions**

Options include:

- **Customer Master Solution** - Purchase/Develop a robust enterprise-wide Customer Master solution (e.g. Siperian) to integrate with other applications (e.g., T&E, CRM, BPM) and manage unique customer profiles

- **Purchase Customer List from external source(s)** – Purchase a master list to use across divisions and systems to align and cross-reference data from multiple sources

- **Create Customer List from internal sources** – Develop and maintain a master list and cross-reference across divisions and systems to align transactions from multiple sources

- Integrate with source systems and 3rd party vendors (for increased accuracy, minimizing follow up and reconciliation) or map and cross-reference after the transaction takes place

- Other Master Data Sources

  - Product/Item Master - Create a standard reference/value list and hierarchy of products and items to be used and referenced consistently across the enterprise

# *Supplement / Remediate Data*

**Ability to capture, enrich or remediate data when sources systems not able to be modified or integrated**

- Options include: Web-based "Portal", ETL-based rules or Manipulation of data directly in data repository to:

  - Add Missing Data

  - Remediate Data Gaps

  - Third-Party Data Entry

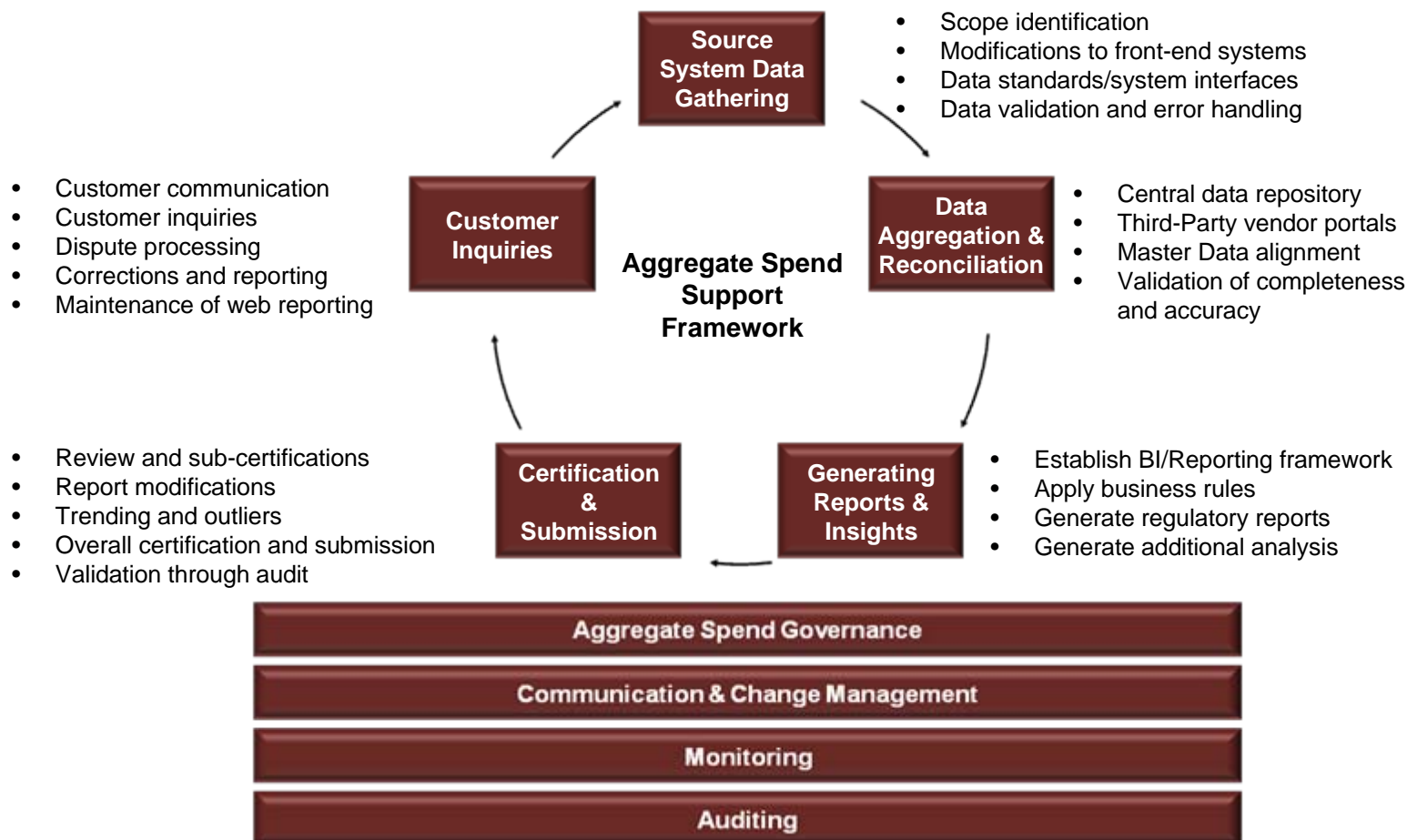  - Align Transactions to Customer Master List

# *Reporting*

**Most source systems of spend data with HCPs/HCIs are designed for purposes other than aggregate spend**

*Therefore, consolidation of POTV transactions at the lowest level of detail in a centralized data repository allows for efficient aggregation, reconciliation, and consistent application of business rules to generate state, federal and internal reports and analytics*

- **Data Repository** – Place to integrate and store detailed spend transactions from multiple source systems

- **Business Rules Engine** – Ability to create and maintain multiple rules for data aggregation, data inclusion, exclusion, and thresholds to address a variety of state & federal requirements

- **Reporting Solution** – Data mart to aggregate data for specific reporting and analytics; pre-configured reporting templates per state and federal requirements; and ad-hoc reporting and analysis capabilities
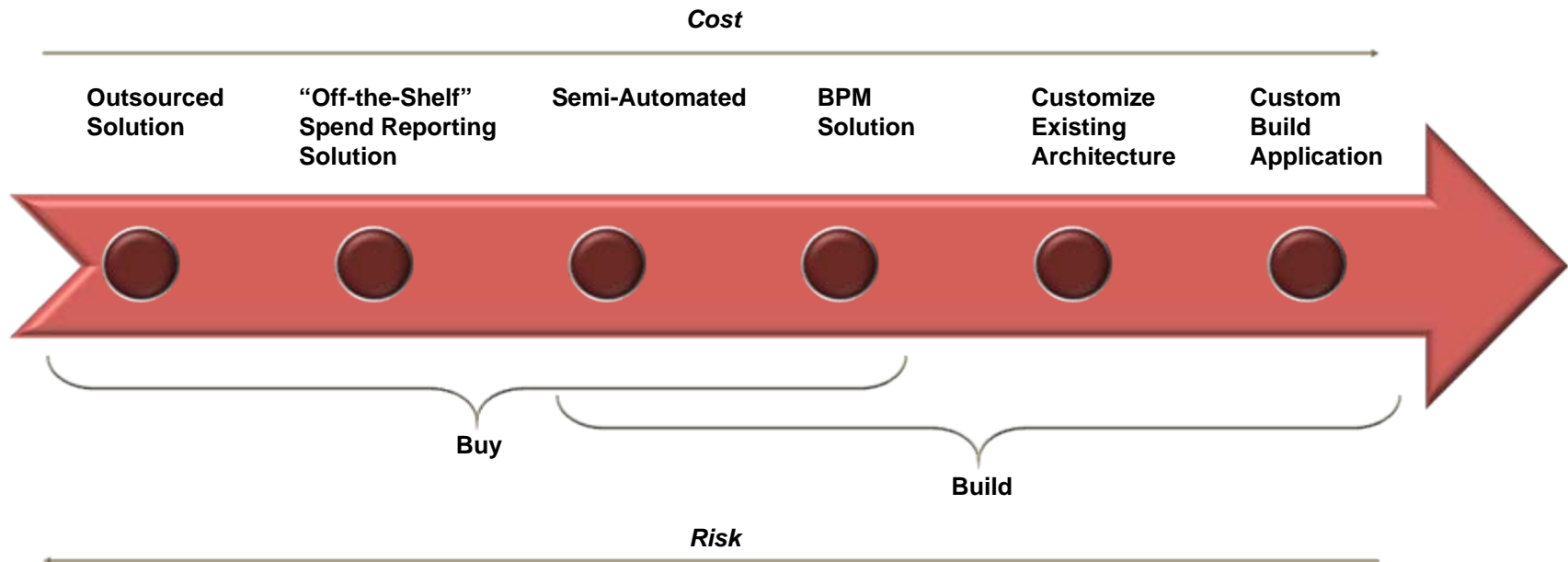
# *Governance*

## New Processes, Standards, and Roles to Support Change

**Source System Data Gathering**
- Scope identification
- Modifications to front-end systems
- Data standards/system interfaces
- Data validation and error handling

**Customer Inquiries**
- Customer communication
- Customer inquiries
- Dispute processing
- Corrections and reporting
- Maintenance of web reporting

**Aggregate Spend Support Framework**

**Data Aggregation & Reconciliation**
- Central data repository
- Third-Party vendor portals
- Master Data alignment
- Validation of completeness and accuracy

**Certification & Submission**
- Review and sub-certifications
- Report modifications
- Trending and outliers
- Overall certification and submission
- Validation through audit

**Generating Reports & Insights**
- Establish BI/Reporting framework
- Apply business rules
- Generate regulatory reports
- Generate additional analysis

**Aggregate Spend Governance**

**Communication & Change Management**

**Monitoring**

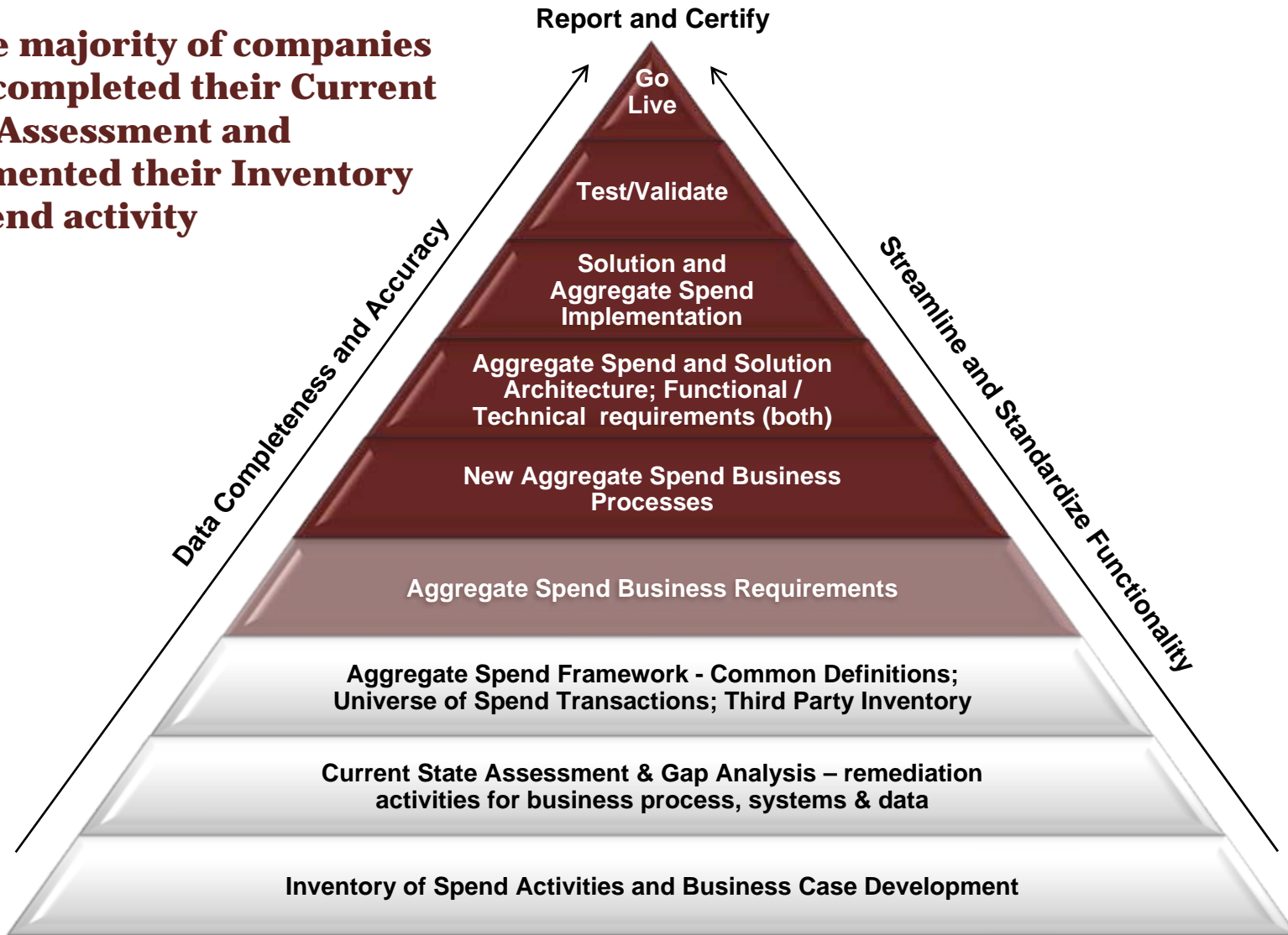**Auditing**

# *Spectrum of options*

**There is no "silver bullet" solution for Aggregate Spend**

*There is a spectrum of options to consider based upon risk appetite and commitment to investment. Thoughtful consideration needs to be given to the design and development of a future state solution that is enterprise-wide, scalable and flexible to evolve with the changing business needs and regulations*



*Cost*

| Outsourced Solution | "Off-the-Shelf" Spend Reporting Solution | Semi-Automated | BPM Solution | Customize Existing Architecture | Custom Build Application |

**Buy**

**Build**

*Risk*

# *Aggregate spend program foundation*

**The majority of companies have completed their Current State Assessment and documented their Inventory of Spend activity**

**Report and Certify**

**Data Completeness and Accuracy**

**Streamline and Standardize Functionality**

- Go Live
- Test/Validate
- Solution and Aggregate Spend Implementation
- Aggregate Spend and Solution Architecture; Functional / Technical requirements (both)
- New Aggregate Spend Business Processes
- Aggregate Spend Business Requirements
- Aggregate Spend Framework - Common Definitions; Universe of Spend Transactions; Third Party Inventory
- Current State Assessment & Gap Analysis – remediation activities for business process, systems & data
- Inventory of Spend Activities and Business Case Development

# *Short-term solution considerations*

**If your long-term vision will not be achieved by the end of 2011, then considerations need to be given to an interim solution development and implementation**

- "Quick wins" to address gaps and gain efficiencies in aggregate spend data collection, processing, and reporting

- Initiation of steps, tools, and templates to achieve the appropriate level of data capture for 1/1/2012

- Communication plans for impacted stakeholders (i.e., internal / external)

- Training of key individuals with known interactions with covered recipients

- Continuation of business behaviors

- Alignment with overall aggregate spend strategy

# *Questions*

# *PwC*

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