

DRAFT



# **Aggregate Spend Disclosure Strategy: Utilizing a Gap Analysis to Advance an Aggregate Spend Program**

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**L I F E   S C I E N C E S   A D V I S O R Y   S E R V I C E S**



# Today's Agenda

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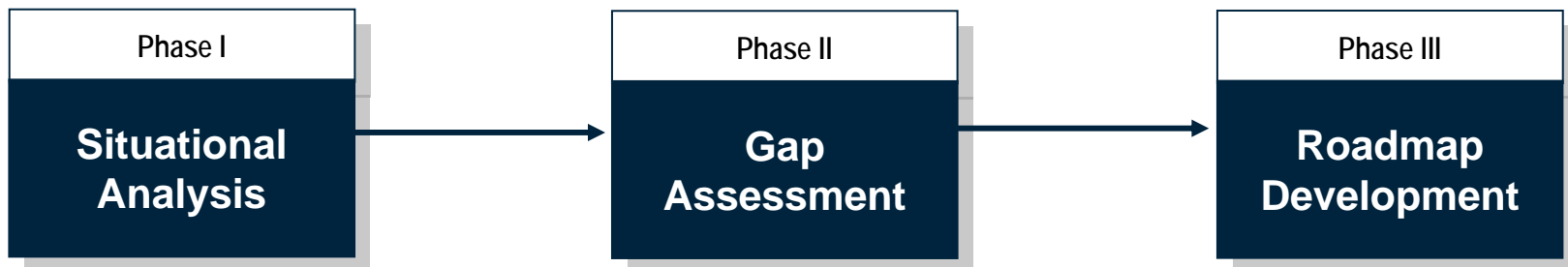
- Defining an Aggregate Spend Gap Assessment
- Next Steps Following an Aggregate Spend Gap Assessment
- Action Items for Your Company

# Aggregate Spend Assessment

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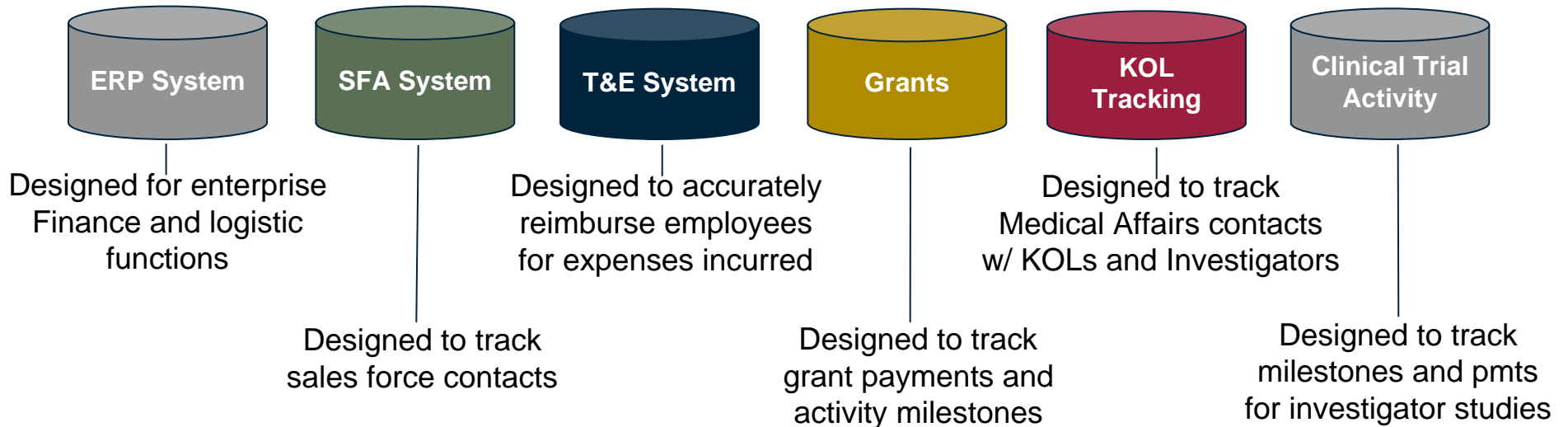
## Assessment Overview

- An increasing number of companies which are affected by HCP/HCO spend reporting regulations have conducted an assessment of their reporting capabilities.
- These assessments may be formal or informal, conducted by an external or internal organization, and often vary in their scope.
- A typical assessment may include the following three phases:



# Aggregate Spend Assessment

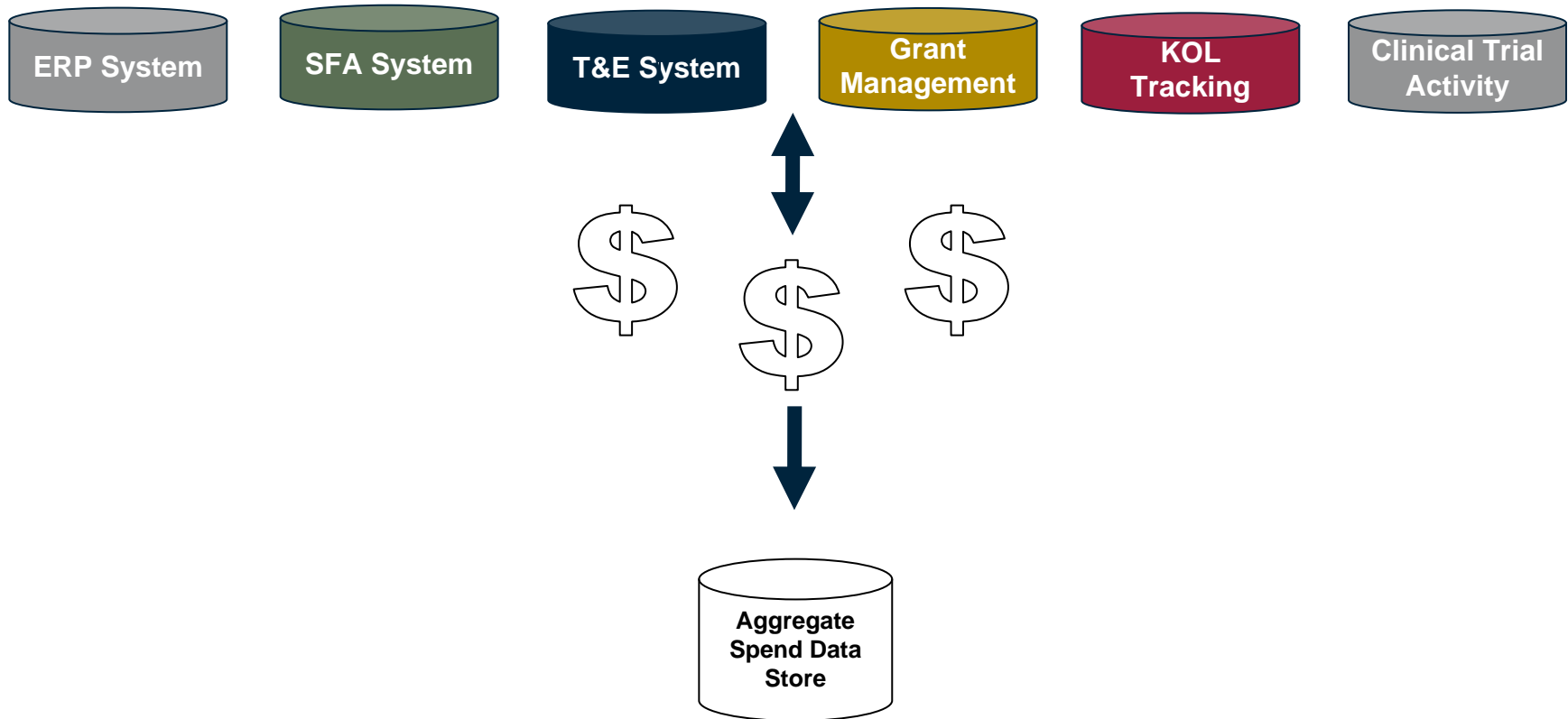
## Review of Source Systems



- Typically, an aggregate spend assessment will include investigating the systems illustrated above to determine the spend data which may be contained within each system.
- Most systems are designed and implemented to meet very specific functional needs or departmental requirements.

# Aggregate Spend Assessment

## Review of Source Systems

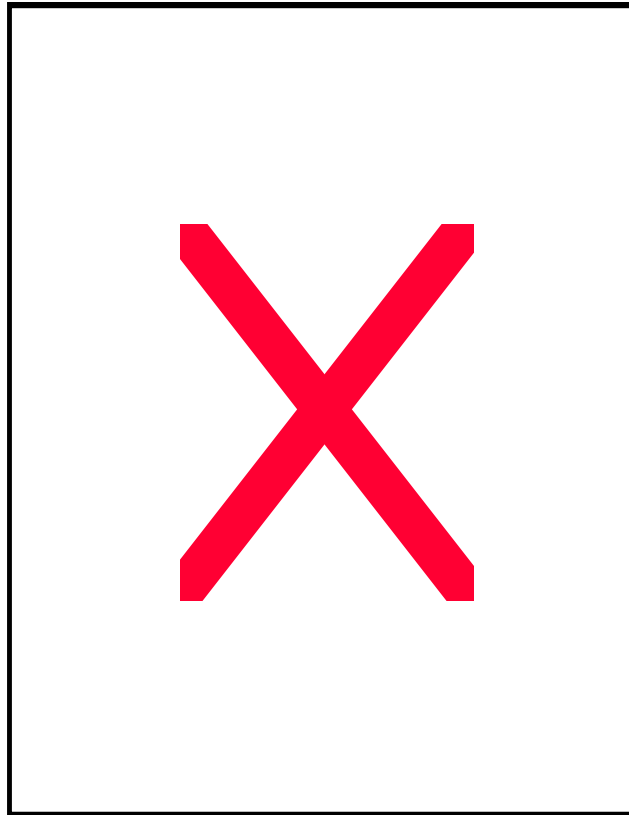


- Frequently, existing source systems may not capture data with the level of granularity necessary for state spend reporting

# Aggregate Spend Assessment

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## Customer Master



- Gap assessments also generally include a review of a company's customer master; a comprehensive customer master promotes reliable and efficient reporting of HCP spending at an individual level.

# Aggregate Spend Assessment

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## Uncovering Hidden Areas of Spend

- An aggregate spend assessment may also uncover many areas of spend which are not currently captured in any existing systems on any level.
- Some of these potential hidden areas of spend include:

Advertisements	Business Development	Demonstration Kits
Educational Materials	E-Marketing	Exhibits (food, giveaways)
Legal (expert testimony)	Managed Markets	Market Research
Pre-Clinical/Clinical	Public Relations	R&D

**Possible International Affiliate and Vendor Spend across many of these areas**

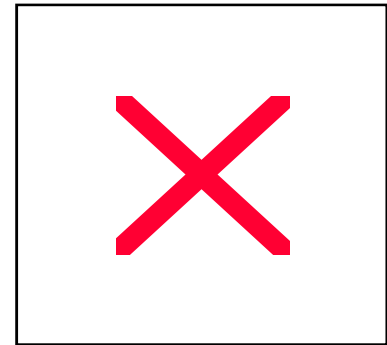
# Next Steps following an Aggregate Spend Assessment

# Next Steps Following an Aggregate Spend Assessment

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## Project Plan Development

- Developing a comprehensive project plan following the completion of an aggregate spend assessment will move companies closer to the target of automated reporting systems and processes.
  - Automation will be critical to a company's ability to comply with the increasing scope of government reporting requirements.
- For each action item identified during the assessment phase, a company should outline:
  - The priority
  - The timeframe for start and completion
  - The business and/or information technology owners
  - Key tasks in order to execute the larger action item
  - In addition, a company should develop a role to oversee the progress of each action item on the project plan.



# Next Steps Following an Aggregate Spend Assessment

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## Project Plan Overview and Representative Project Plan

- At a high level, an aggregate spend project plan can be divided into “Requirements Development” and “Implementation” phases; each area of risk uncovered by the gap assessment will need to be addressed in this plan.
  - During the requirements phase, minor system changes will be executed; policies will be updated; and, architectures / business rules for major systems will be developed.
  - During the implementation phase, required systems will be built out based off of the architectures / business rules established in the Requirements phase.
- Across both phases, the project management function will coordinate with key stakeholders to maintain each action item’s timeliness.



# Next Steps Following an Aggregate Spend Assessment: Action Items

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## Business / Legal Decisions

- Utilizing a gap assessment, companies should consider what they want or need to track from both a legal and business perspective.
  
- In making these determinations, Companies should consider both what is currently required (including states and specific laws) and potential upcoming requirements.
  
- Examples of these decisions could include:
  - Whether or not journal reprints and other educational materials must be tracked and assigned a value
  - How spending from international affiliates on US HCPs will be tracked and reported
  - How spending from co-promotion partners will be tracked and reported
  - Whether or not market research payments could or should be reported

# Next Steps Following an Aggregate Spend Assessment: Action Items

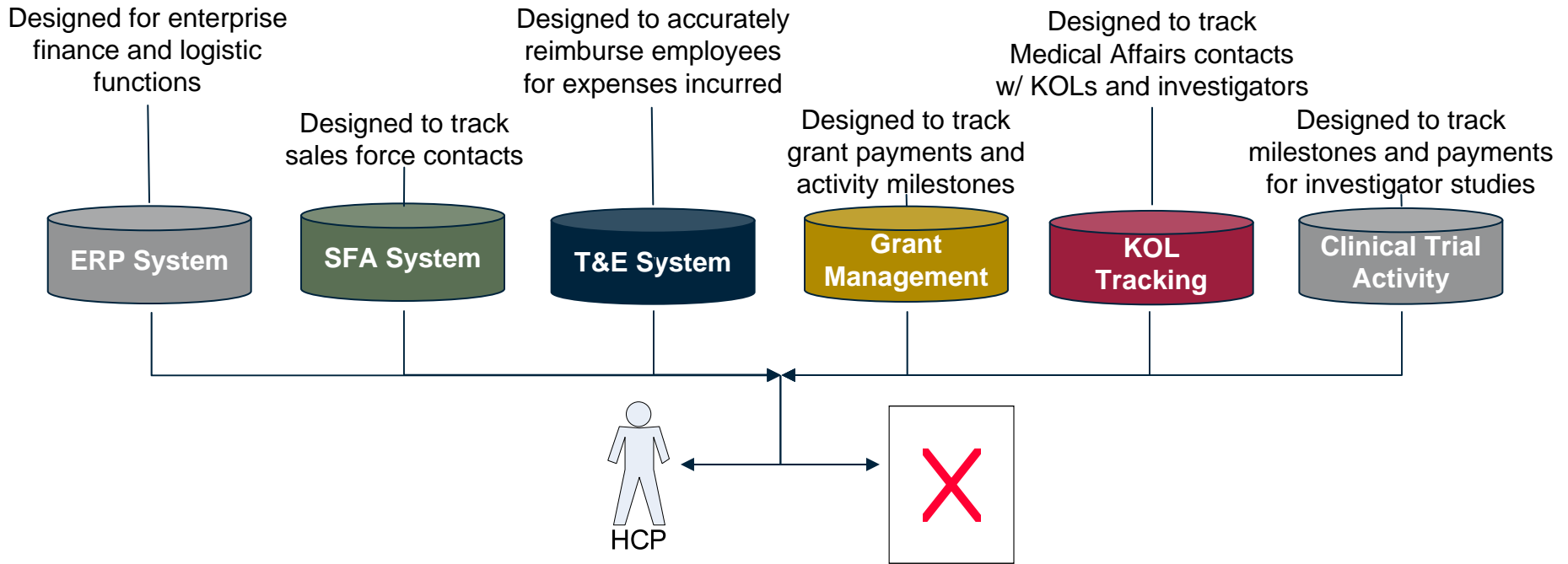
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## Obtaining Stakeholder Buy-In

- Having buy-in from relevant company stakeholders will be imperative in order to accomplish tasks related to your company's aggregate spend assessment.
- Senior leadership can emphasize the importance of accurate aggregate spend data collection; this leadership should include senior management from:
  - Compliance
  - Finance
  - Information Systems
  - Legal
  - The Reporting Function, if applicable
  - Other relevant functional areas

# Next Steps Following an Aggregate Spend Assessment: Action Items

## Source Systems



- Organizations must address state reporting requirements and aggregate spend tracking needs through short-term process improvements to improve data capture and medium to long-term system enhancements to increase reporting efficiency and accuracy.
- Many of these systems will require changes and updates to be able to properly capture spend data.

# Next Steps Following an Aggregate Spend Assessment: Action Items

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## Customer Master

- Having a central Customer Master of HCPs and HCOs across the organization for reporting and tracking is imperative for accurate spend allocation.
- As part of the gap assessment a Company's customer master should have been reviewed.
- Companies should consider the following questions and action items:
  - Decide on the individuals that will need to be a part of this customer master (that is, who is an HCP and HCO) required internally and by state/federal laws
  - Determine information required for the customer master (e.g. address, affiliate information, state licensure numbers, or government employee information)

# Next Steps Following an Aggregate Spend Assessment: Action Items

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## Aggregate Spend Tools

- One of the biggest decisions after a gap assessment is determining if a company requires an aggregate spend tool to facilitate and automate these reporting and tracking requirements.
  
- If a company decides that a tool is necessary, the company will need to determine if they are going to purchase a tool or build their tool internally.
  - Both options are possible
  - There are several vendors who offer Aggregate Spend Tools
  - Several life science companies have chosen to build their own system for tracking Aggregate Spend

# Next Steps Following an Aggregate Spend Assessment: Action Items

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## Purchasing an Aggregate Spend Tool

- Should a company chose to purchase an operational data store / reporting system from an external vendor, the company should consider developing a dedicated vendor selection Committee.
  - This vendor selection should be comprised of individuals with relevant expertise, namely:
    - Information Systems
    - The Reporting Function, if applicable
    - Company individuals who are experienced with state reporting / operational data store solutions
  
- Vendor selection will be a critical step to promoting a company's reporting efforts; companies may wish to develop a Vendor Scorecard which would be based off of each company's individualized needs and would enable objective scoring and selection of an appropriate vendor.

# Next Steps Following an Aggregate Spend Assessment: Action Items


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## Building an Aggregate Spend Tool

- Building an aggregate spend tool is possible by utilizing existing systems.
  
- This may be an option explored during the gap assessment process.
  
- Some of advantages of using a home grown system may be:
  - Cultural awareness
  - Understanding of internal systems
  - Cost savings
  - Easier system integration due to system understanding

# Task Assignment

## Action Item Checklist



**Key Tasks Related to  
Your Aggregate Spend Assessment**


**Assessment Phase**

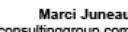
- Has buy-in from necessary stakeholders been obtained?  Yes  No
- Has the Company determined if the assessment will be conducted by an internal or external organization?  Yes  No
- Have the following systems been reviewed to determine if they contain spend data and, if so, if the data has the necessary level of detail for reporting:
  - ERP System
  - SFA System
  - T&E System
  - Grants System
  - KOL Tracking Tool
  - Clinical Trial Management System
  - Other Relevant Systems
- Has the Customer Master been assessed, and have any changes necessary to uniquely identify HCPs been determined:  Yes  No
- Have the following areas been examined for hidden spend:

<ul style="list-style-type: none"><li><input type="checkbox"/> Advertisements</li><li><input type="checkbox"/> Business Development</li><li><input type="checkbox"/> Demo Kits</li><li><input type="checkbox"/> Educational Materials</li><li><input type="checkbox"/> E-Marketing</li><li><input type="checkbox"/> Exhibits</li></ul>	<ul style="list-style-type: none"><li><input type="checkbox"/> Legal</li><li><input type="checkbox"/> Managed Markets</li><li><input type="checkbox"/> Market Research</li><li><input type="checkbox"/> Pre-Clinical/Clinical</li><li><input type="checkbox"/> Public Relations</li><li><input type="checkbox"/> R&amp;D</li></ul>
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**Post-Assessment Phase**

- Has a project plan been developed with:
  - Stakeholders identified for all tasks
  - Tasks prioritized
  - Key start and end dates identified
  - A program lead/manager assigned
- Have key business/legal decisions been identified?  Yes  No
- Has buy-in from necessary stakeholders been obtained?  Yes  No
- Have required changes to source systems been identified?  Yes  No
- Have required changes to the customer master been identified?  Yes  No
- Has a decision been made to buy or build an aggregate spend tool?  Yes  No
  - If a decision has been made to buy a solution, has a vendor selection committee been formed?  Yes  No

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# Questions?

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