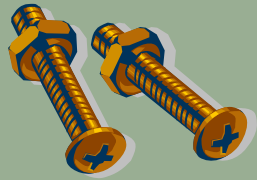




The National Disclosure Summit

The Leading Forum on Disclosure, Transparency and Aggregate Spend for Drug, Device and Biotech Companies



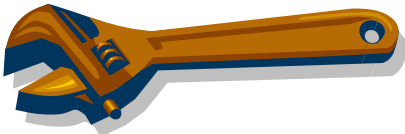
The Nuts and Bolts of an Aggregate Spend PMO

Working in Harmony across Process,
Technology, and Change Management

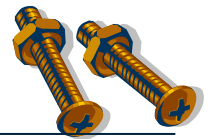


Manny Tzavlakis, Managing Director
Leanne DiDomenico, Manager
Joseph Morrell, Manager

Establishing an Aggregate Spend PMO



Establishing an Aggregate Spend PMO



Goals and Challenges

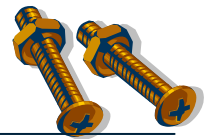
Goals

- ❖ Promote functional area ownership of aggregate spend data entry and management
- ❖ Facilitate major decisions regarding spend entry processes and systems
- ❖ Monitor the progress of individual workstreams against disclosure timelines
- ❖ Prepare the organization for the repercussions of disclosure
- ❖ Ultimately, oversee the transition to ongoing, day-to-day disclosure operations










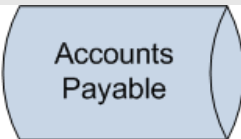



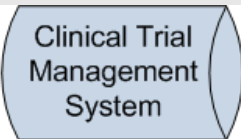
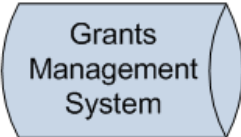
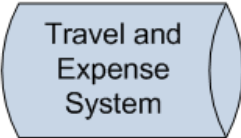

Key Challenges

- ❖ Obtaining executive sponsorship and *acceptance and commitment* from employees
- ❖ Evaluating the costs and benefits of data automation vs. manual entry
- ❖ Maintaining visibility to project delays, risks, and planned actions
- ❖ Driving necessary operational and organizational changes
- ❖ Promoting collaboration and efficiencies across all project workstreams

Establishing an Aggregate Spend PMO



Identifying Program Management Leadership Committee Membership: A Checklist

Program Management Leadership Committee			
Business		Technical	
<input checked="" type="checkbox"/>	 Clinical / R&D Representation for R&D, Ph. I-IV Trials, Inv. Sponsored Trials	<input checked="" type="checkbox"/>	 Marketing Brand Director for each Brand / T.A.
<input checked="" type="checkbox"/>	 Compliance Compliance Director / Compliance Officer	<input checked="" type="checkbox"/>	 Medical Medical Information / Field Medical Mgr
<input checked="" type="checkbox"/>	 Finance A/P Director	<input checked="" type="checkbox"/>	 Operations Manager for Samples and other activities
<input checked="" type="checkbox"/>	 Grants Manager of Grants and Sponsorships	<input checked="" type="checkbox"/>	 Sales Sales Director for each Brand / T.A.
<input checked="" type="checkbox"/>	 International Intl. Compliance / Other person familiar with intl. spending on US HCPs and HCOs		
		<input checked="" type="checkbox"/>	 Accounts Payable
		<input checked="" type="checkbox"/>	 Field Medical Tool / KOL Tracker
		<input checked="" type="checkbox"/>	 Sales Force Automation Tool
		<input checked="" type="checkbox"/>	 Customer / Vendor Master
		<input checked="" type="checkbox"/>	 Clinical Trial Management System
		<input checked="" type="checkbox"/>	 Grants Management System
		<input checked="" type="checkbox"/>	 Travel and Expense System
		<input checked="" type="checkbox"/>	 Product / Educational Item Master

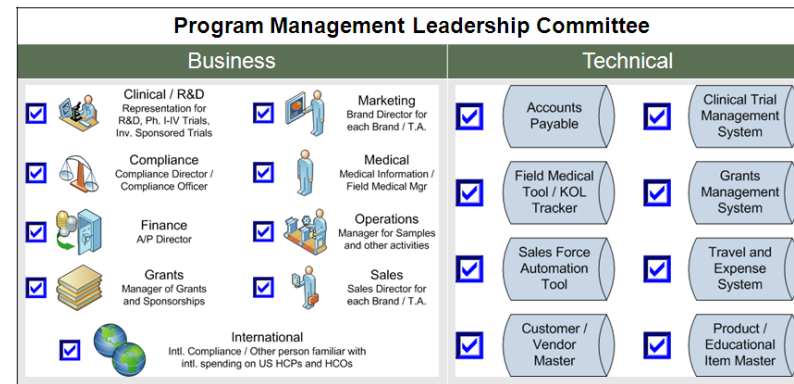
Additional stakeholders may be necessary depending on your company's structure.

Establishing an Aggregate Spend PMO



Obtaining Support and Driving Results

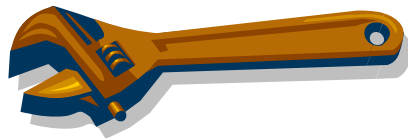
To meet the PMO's goals, stakeholders from each functional area will need to be engaged and *committed to driving the success* of the aggregate spend initiative.



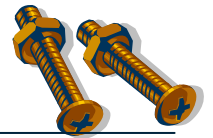
PMO Leadership Responsibilities

- Within each functional area, message the importance of the initiative
- Manage funding and staffing needs for aggregate spend compliance
- Provide input and guidance on the key decisions affecting each functional area
- When necessary, ensure the timely completion of aggregate spend process and technology changes
- Consider the strategic impact of disclosure on each functional area and on the organization as a whole

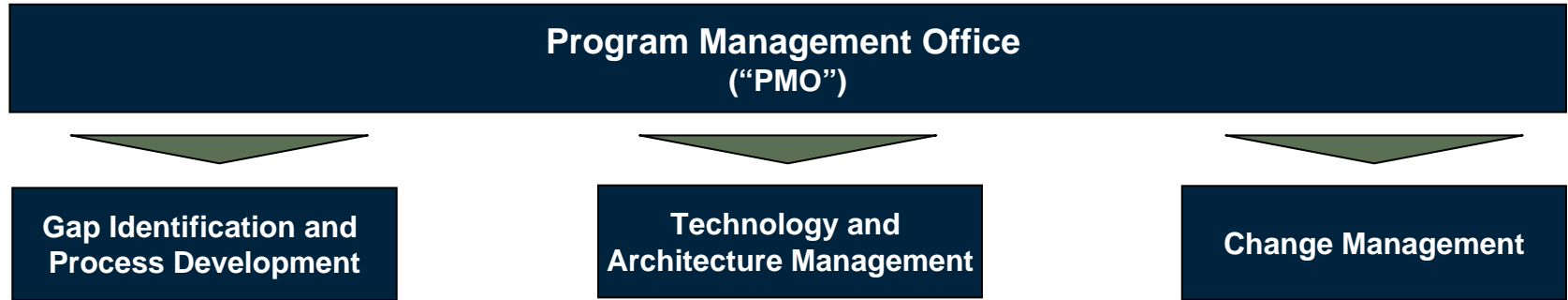
Harmonizing Process, Technology, and Change Management



Harmonizing Process, Technology, and Change Management



Overview of Process, Technology, and Change Management Goals



Project Workstream	Goals
A. Gap Identification and Process Development	<ol style="list-style-type: none"> 1. Inventory where relevant spending resides and analyze gaps in its collection 2. Determine which spend will be captured manually and which will be automated 3. Develop processes to manage the capture of all relevant spend data
B. Technology and Architecture Management	<ol style="list-style-type: none"> 1. Develop future design state based on aggregate spend business requirements 2. Oversee system modifications and development 3. Ensure alignment across all relevant vendors
C. Change Management	<ol style="list-style-type: none"> 1. Transition individuals, teams, departments, and company affiliates from the current state to the future design 2. Motivate and educate employees about change and reinforce proper behaviors 3. Manage key decisions which are on the critical path of the project

Harmonizing Process, Technology, and Change Management



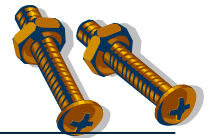
Outlining a High-Level Workplan and Addressing Resource Needs

ID	Task Name	Workstream	Apr 2011				May 2011				Jun 2011				Jul 2011				Aug 2011				Sep 2011				
			4/3	4/10	4/17	4/24	5/1	5/8	5/15	5/22	5/29	6/5	6/12	6/19	6/26	7/3	7/10	7/17	7/24	7/31	8/7	8/14	8/21	8/28	9/4	9/11	9/18
1	Establish Leadership Committee	Change Management	█																								
2	Conduct Gap Analysis	Process Development		█	█	█	█	█																			
3	Develop High-Level Architecture	Technology and Architecture		█	█																						
4	Produce Manual/Automation Analysis	Process Development						█	█																		
5	Oversee System Modifications	Technology and Architecture																									
6	Develop Detailed Processes	Process Development																									
7	Conduct Organizational Assessment	Change Management																									
8	Manage Employee Training	Change Management																									
9	Transition to "Steady State"	Change Management																									

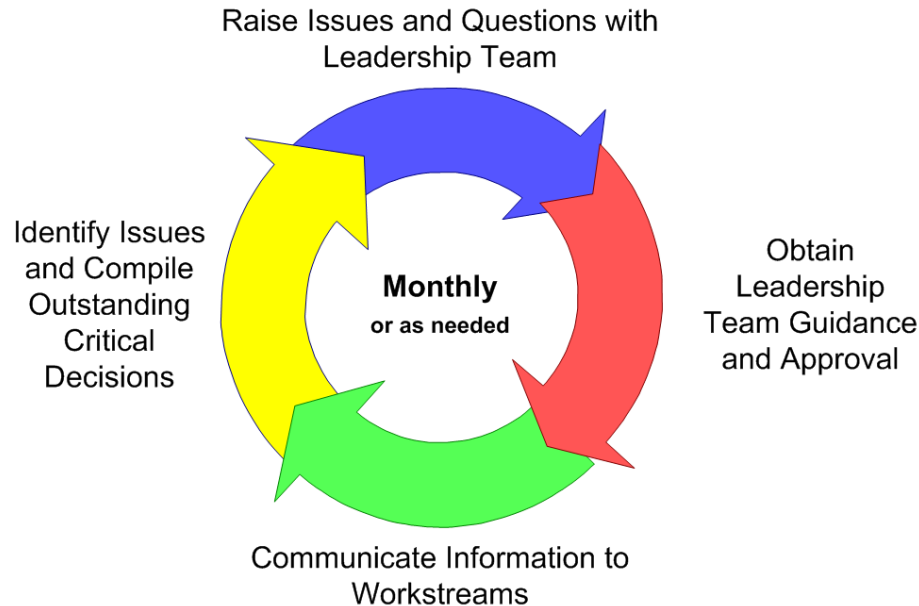
High-Level Workplan

- Consider working backwards from targeted system go-live date to outline the high-level responsibilities of each workstream
- Develop a high-level workplan before attempting to produce a detailed, task driven plan which the PMO will ultimately manage against. This will:
 - ✓ Enable resource constraints to be identified
 - ✓ Allow for funding to be established on a quarterly basis
 - ✓ Produce phases and goals which can easily be understood across the company

Harmonizing Process, Technology, and Change Management



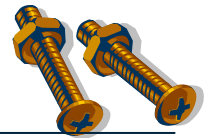
Continuing Stakeholder Involvement



A primary function of the PMO is to escalate critical issues to the Leadership Team and shepherd those issues and questions through the decision-making process. Ensuring that all critical issues and questions flow through the PMO will increase efficiency and executive satisfaction with the project.

Ensuring continued Leadership Team involvement is critical to the proper resourcing, guidance, and success of the project.

Harmonizing Process, Technology, and Change Management



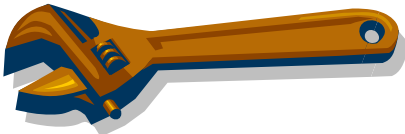
Promoting Information Transfer across Workstreams

Communicating information across individual Aggregate Spend workstreams is a second key function of the PMO. Timelines, risk, and resourcing can be managed via PMO ownership of the following tools:



- 🔧 **Risk Log** to catalog risks and prioritize them for elevation to Compliance or the Leadership Team
- 🔧 **Action Log** to promote accountability to milestones outlined in the project plan
- 🔧 **Project Plan** to ensure that cross-workstream schedule dependencies are being maintained
- 🔧 **Status Reports** to ensure that each workstream is aware of relevant key milestones that have been reached in other workstreams

Results

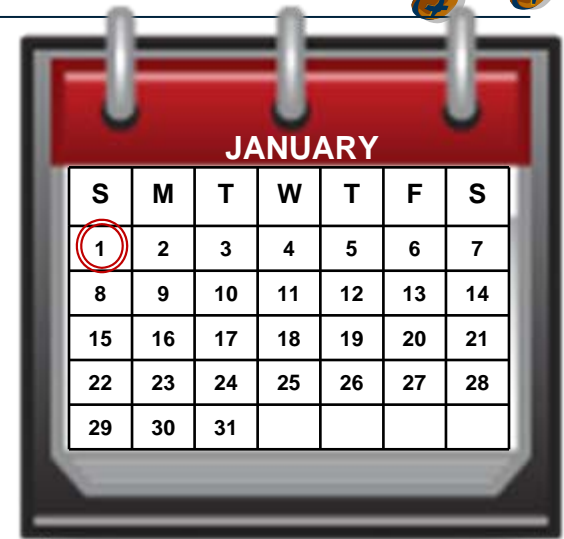


Results



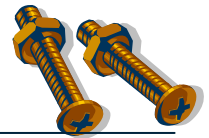
Review: Driving Success

How can your Aggregate Spend PMO drive your organization toward its goal of capturing all relevant aggregate spend data by January 1, 2012?



- **Develop Ownership and Sponsorship** via a Leadership Team which will meet on a regular basis.
- **Coordinate Resources and Budget** by establishing a high-level project plan and observing where bottlenecks may occur
- **Promote Accountability to Goals and Targets** by developing a detailed work plan and reviewing it with individual workstream owners regularly
- **Communicate Key Actions, Issues, and Risks** by using the tools outlined in the “PMO Toolkit”
- **Ensure that the Organization is Ready for Disclosure** by managing the development of an “Aggregate Spend 2.0” strategy

Results



Aggregate Spend 2.0

Compile Accurate Data

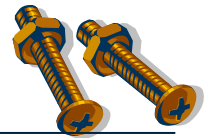
- The initial function of the PMO is to ensure that accurate, complete aggregate spend data can be compiled effectively.
- As the project nears its end, the PMO must prepare the organization for the “steady state”

Prepare for HCP Data Disclosure Preview

- Work with communications and training to develop materials preparing both field employees and HCPs for data disclosure
- Work with operations to develop operating parameters for the HCP Dispute Center






Manage HCP Data Disputes

- Ensure that HCP disputes are being routed appropriately and are being resolved timely and in accordance with company policy
- Consider allowing HCPs to set “spend limits” or to opt out of certain spend types

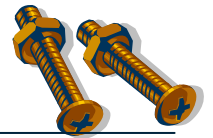


Huron's Lessons Learned

Best Practices

-  **Establish a strong and committed Leadership Team *at the beginning of the project***
-  **Empower employees to make non-critical decisions in a timely manner**
-  **Ensure that critical decisions are addressed by the Leadership Team regularly and effectively in order to maintain project timelines**
-  **Promote inter-workstream dialogue and communications through efficient use of status reports and risk and action logs.**
-  **Your best practices to date...?**

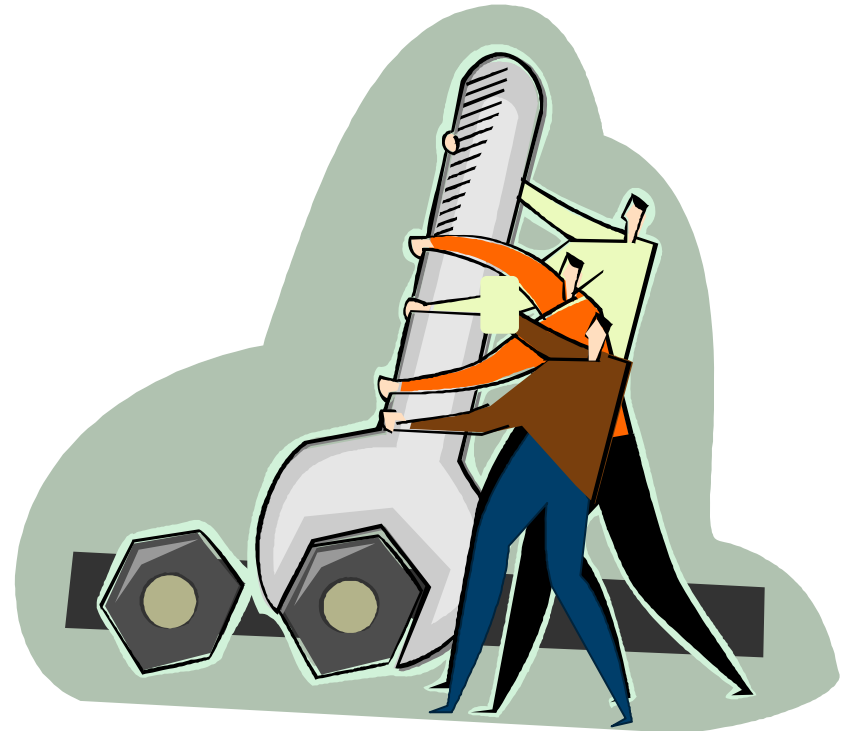
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