



Making Change Stick: The Importance of Driving Results and Follow Ups From Monitoring Activities

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**FOURTEENTH ANNUAL PHARMACEUTICAL
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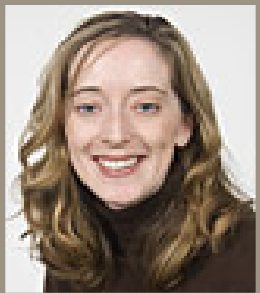
Panel Introduction



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Making Change Stick: Three Key Elements

To make change “stick,” three essential elements must be in place:

- A strong compliance governance structure
 - Policies and procedures that are well-documented and upon which relevant personnel are well-trained
 - Individuals and leaders who emphasize the desired behaviors

- A robust monitoring program

- *A consistent, standardized investigations and corrective actions process designed to create and reinforce organizational accountability for compliant operations*

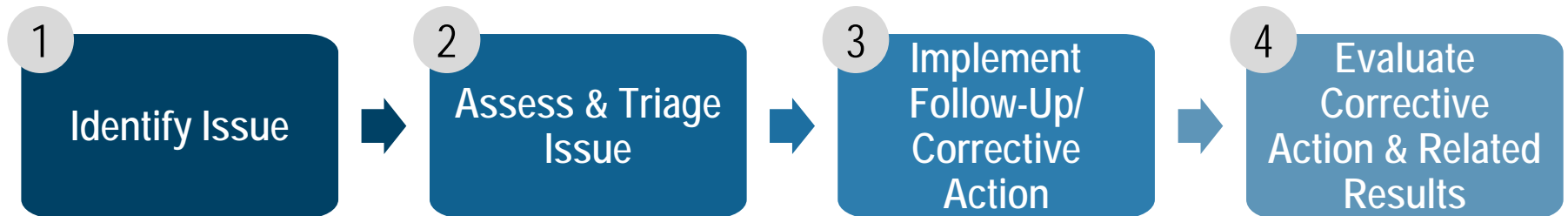
I Don't Operate Under a CIA – Why Do I Care?

- Strong trend towards transparency is taking your assessment of your own company's compliance out of your hands
- Open Payments and ClinicalTrials.gov are only the beginning – the government, media, and watchdog groups are actively mining public data to find out if you're doing the right thing – you should be doing so, too
- Given regulation trends all companies should establish a formalized monitoring and investigations process



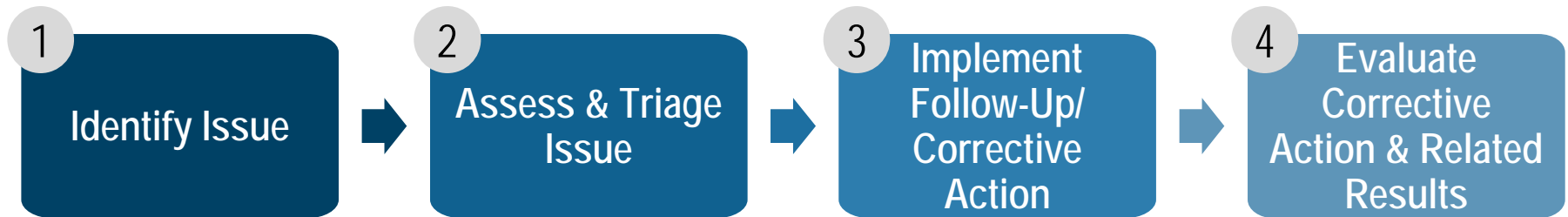
Investigations Process Breakdown

Below is a high-level version of an Investigations and Corrective Actions process flow.



- The formality of the investigations process and framework may vary based on your company's needs
- For any investigations process, the key is ensuring that the process is:
 - Rooted in compliance with your policies
 - Consistently applied
 - Well-understood

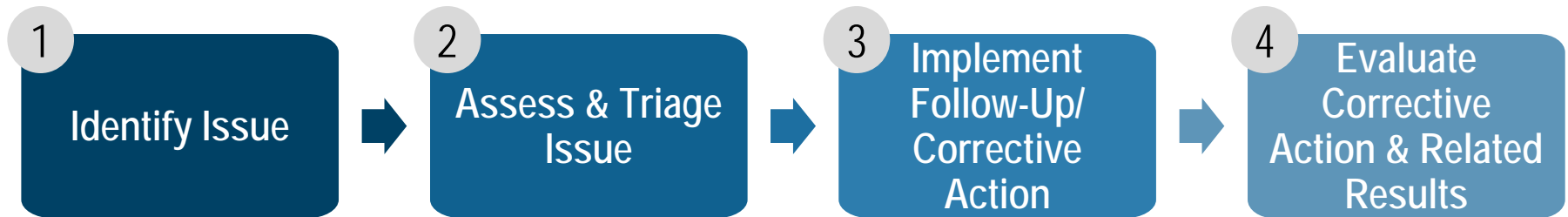
Step 1: Identify Issue



KEY CONSIDERATIONS

- Identify triggers
- Create link between case management capability and investigations
- Reporting/metrics

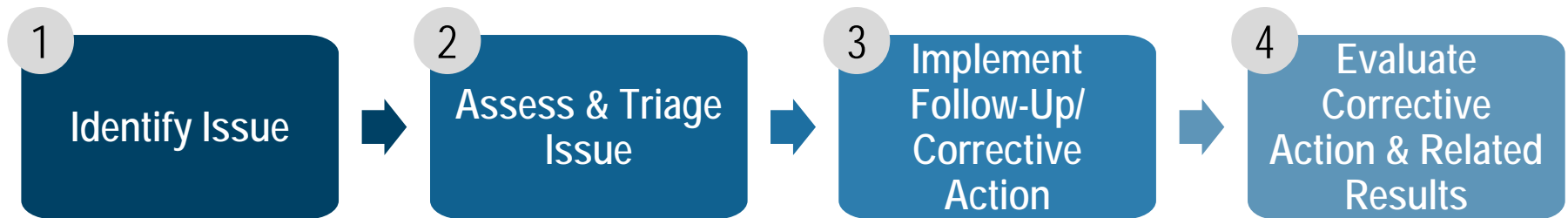
Step 2: Assess & Triage Level of Risk



KEY CONSIDERATIONS

- Create well-understood, cross-functional issue triage process
- Ensure that issues are responded to in a consistent manner

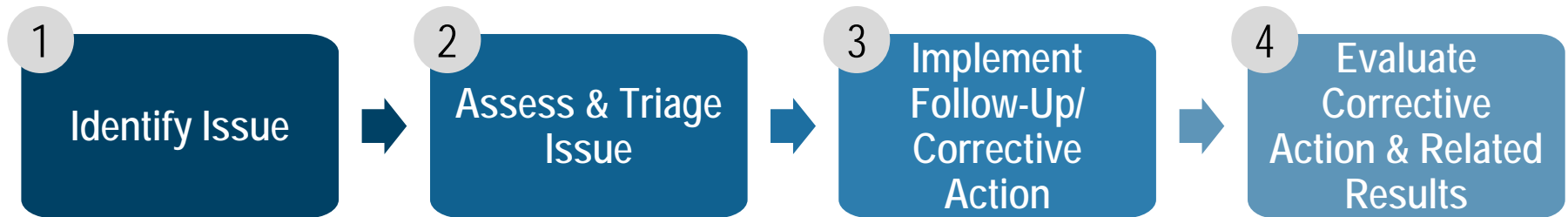
Step 3: Implement Follow-Up/Intervention



KEY CONSIDERATIONS

- Define and communicate follow-up/corrective action process ownership
- Ensure actions take place as outlined in the investigations process

Step 4: Evaluate Intervention & Related Results



KEY CONSIDERATIONS

- Measure whether and to what degree the behavior changed
- Capture results to improve future mitigation activities

When Training & Communication is Not Enough

Ways to Build Employee Accountability

- Link behaviors to incentive compensation models
- Retrain staff (as necessary)
- Re-monitor (as necessary)
- Hold supervisors accountable
- Establish a disciplinary model – once you've gotten past the training, communication, retraining
 - Implement a strong, well-articulated system to address issues and define repercussions of non-compliance
- Educate the business on compliance compensation drivers, and risks to the business and individual for policy violations

Put In Place a Corrective Action Process

Define Metrics:

Outline tolerance thresholds based on level of violation. Assign each violation level to a corrective action process.

Outline Roles:

Identify who is accountable, responsible, informed and/or consulted in escalation and administration of the corrective action plan.

Develop Process:

Determine appropriate remediation activities based on violation level. Ensure actions are properly documented & traceable for audit history purposes.

Corrective Action Plan

Define who owns the plan & ensure it is properly documented within a policy (existing or new).

Engage Supervisors, Leadership & HR

How long will the violation be tracked? Who owns tracking within the business?

 **1 violation**

LOW

Supervisor notified

Required to re-read and attest to company policies

 **2 violations**

MEDIUM

Coaching session with supervisor

Required to redo training on company policies

Supervisor submits certification form once coaching and training completed

 **3 violations**

HIGH

Business leader & supervisor required to contact HR

Formal warning letter provided to employee

Coaching meeting to discuss potential performance impacts

Supervisor submits certification form once coaching is complete

> 3 violations

HR disciplinary action up to and including termination as management deems appropriate.

Questions or Comments

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Questions

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