How Risk Assessment and Compliance Program Effectiveness

Tie Together:

A Joint Perspective from the Chief Compliance Officer and Director of Internal Audit

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How Risk Assessment and Compliance Program Effectiveness Tie Together
A Joint Perspective from Compliance and Internal Audit



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Disclaimer

The opinions expressed are those of the presenters and are not intended to be statements or reflections of the opinions or positions of their employer.

This presentation is general in scope, seeks to provide relevant background and hopes to assist in the identification of pertinent issues and concerns. The information is not intended to be, nor should it be construed or relied upon, as legal advice.

The presenters did not receive compensation from any vendors or consulting firms referenced during the presentation.

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Shameless Plug



Saint Peter's Healthcare System, New Brunswick, NJ

- 478-bed acute-care NFP Hospital
- State-Designated acute-care Children's Hospital
- Workforce of ~3,800, including Employed Providers
- 128 Residents & Fellows; 104 Employed
- 26,000 Inpatients and Observations in 2025
- 5,448 Babies Delivered in 2025
- 84,000 visits to Family Health Center in 2025
- 64,000+ ED visits in 2025
- 2025 Revenue $651 Million
- Safety Net – Delivered $102M in Community Benefit in 2025

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Learning Objectives

- Explain why compliance risk assessments are foundational to an effective compliance program
- Describe the components of an effective compliance program
- Understand how Internal Audit complements Compliance
- Identify best practices for conducting a healthcare compliance risk assessment
- Recognize how continuous improvement strengthens compliance effectiveness

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The Healthcare Compliance Landscape

Healthcare organizations face increasing complexity.

Today's risks include:

- OIG enforcement priorities
- DOJ expectations
- CMS reimbursement changes
- HIPAA cybersecurity threats
- Physician arrangements
- Quality and patient safety
- AI and emerging technologies
- Workforce shortages
- Third-party vendors



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Why Compliance Matters

Compliance is not just avoiding penalties.

It supports:

- Patient safety
- Quality care
- Ethical culture
- Public trust
- Financial stability
- Organizational reputation
- Mission fulfillment

Compliance is a strategic business function—not simply a regulatory requirement.

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Regulatory Expectations Have Changed

Years ago regulators asked:

"Do you have a compliance program?"

Today they ask:

"Is your compliance program effective?"

DOJ

OIG

Federal Sentencing Guidelines

All focus on effectiveness—not existence

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What Does an Effective Compliance Program Look Like?

- Identifies risks
- Prevents violations
- Detects problems early
- Responds quickly
- Corrects root causes
- Continuously improves



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Seven Elements of an Effective Compliance Program



1. Standards & Policies
2. Compliance Oversight
3. Education and Training
4. Monitoring & Auditing
5. Reporting & Investigating
6. Enforcement & Discipline
7. Response & Prevention

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Leadership & Governance

An effective compliance program begins at the top.

Leadership responsibilities include:

- Tone at the Top
- Resource allocation
- Independence
- Board reporting
- Accountability

Questions Boards should ask

- What are our top compliance risks?
- How were they identified?
- Are resources aligned?
- What trends are emerging?
- How do we know the program is effective?

Culture Drives Compliance

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Independence of Compliance

Compliance should have:

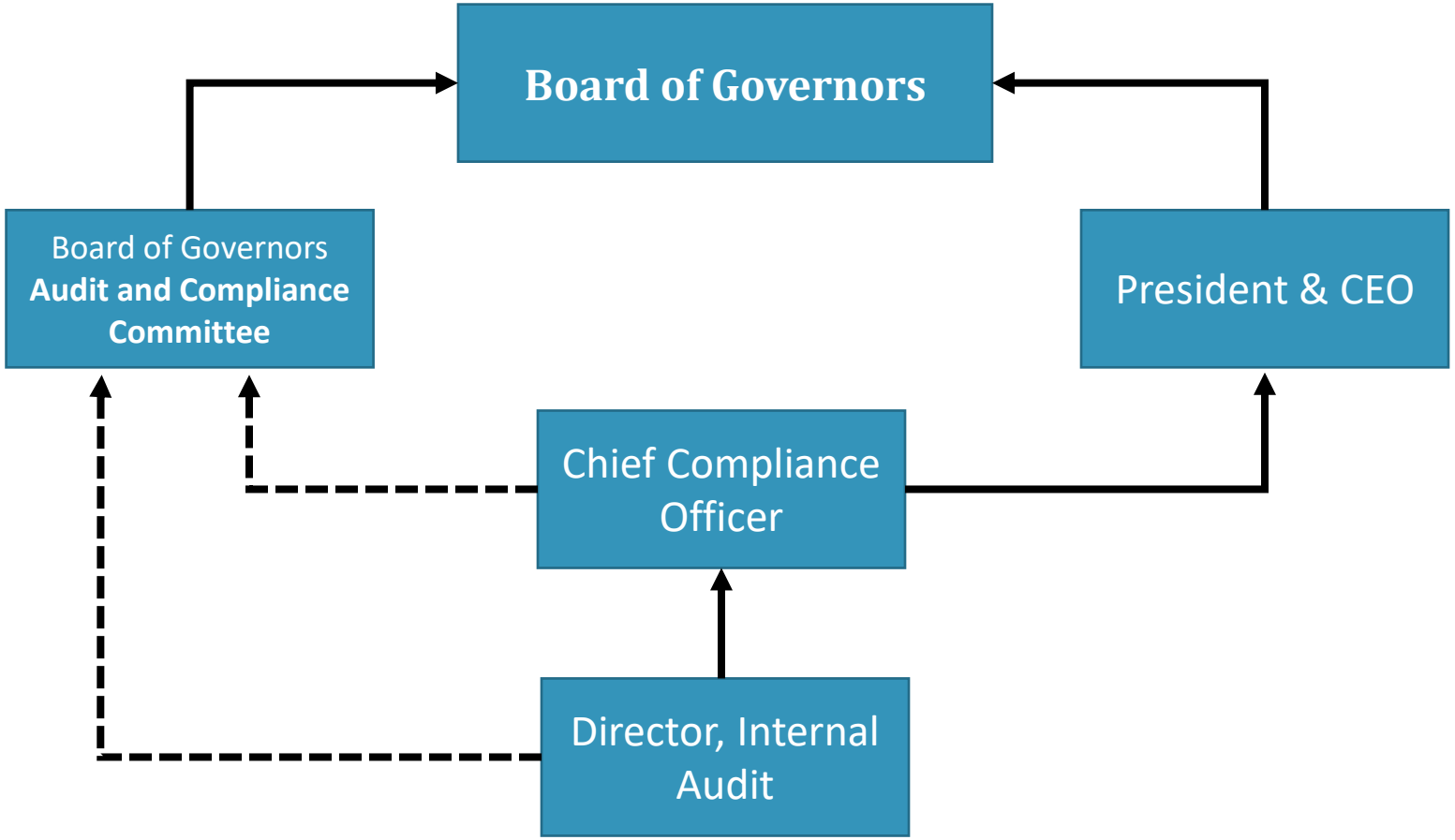
- Direct access to CEO
- Regular Board reporting
- Authority to investigate
- Adequate staffing
- Freedom from operational influence



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Where Does Compliance and Audit Report in your Organization



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The Foundation of the Compliance Program

Everything begins here.

Without understanding risk—

Resources cannot be prioritized.

Monitoring becomes reactive.

Audit plans lose focus.

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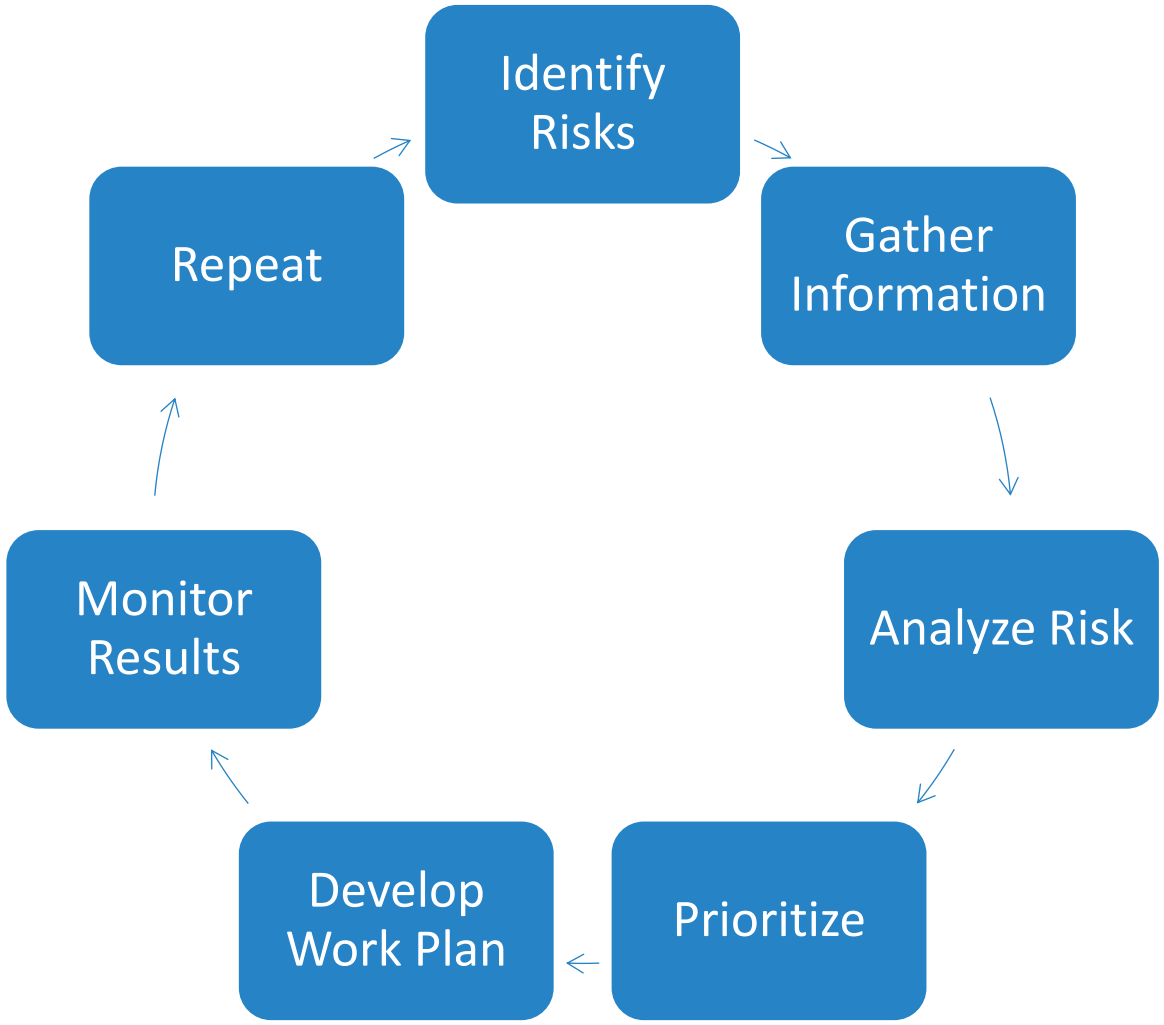
Why Risk Assessments Matter

- Risk-based
- Data-driven
- Collaborative
- Objective
- Repeatable
- Documented
- Updated annually
- Dynamic—not static

Characteristics of an Effective Risk Assessment

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Risk Assessment Process



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Risk Assessment Process

Step 1: Identify Risks

- Clinical Operations
- Revenue Cycle
- Privacy
- Research
- Quality
- Cybersecurity
- Supply Chain
- Human Resources
- Vendor Management
- Graduate Medical Education

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Risk Assessment Process

Step 2: Gather Information

Multiple information sources should be used

Internal Data Sources

- Hotline trends
- Incident reports
- Patient complaints / Employee concerns
- Corrective actions
- Denied claims
- Coding reviews / Billing edits
- Prior audits
- Monitoring reports

- OIG Work Plan
- DOJ guidance
- CMS regulations
- NJ DOH
- NJ Medicaid
- Hotline reports
- Internal investigations
- Audit reports
- Claims data
- External benchmarking
- ERM results

OIG Workplan

Explain how organizations should routinely review:

- New audit priorities
- Fraud trends
- Billing risks
- Provider vulnerabilities
- Emerging enforcement topics

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Interview Leadership

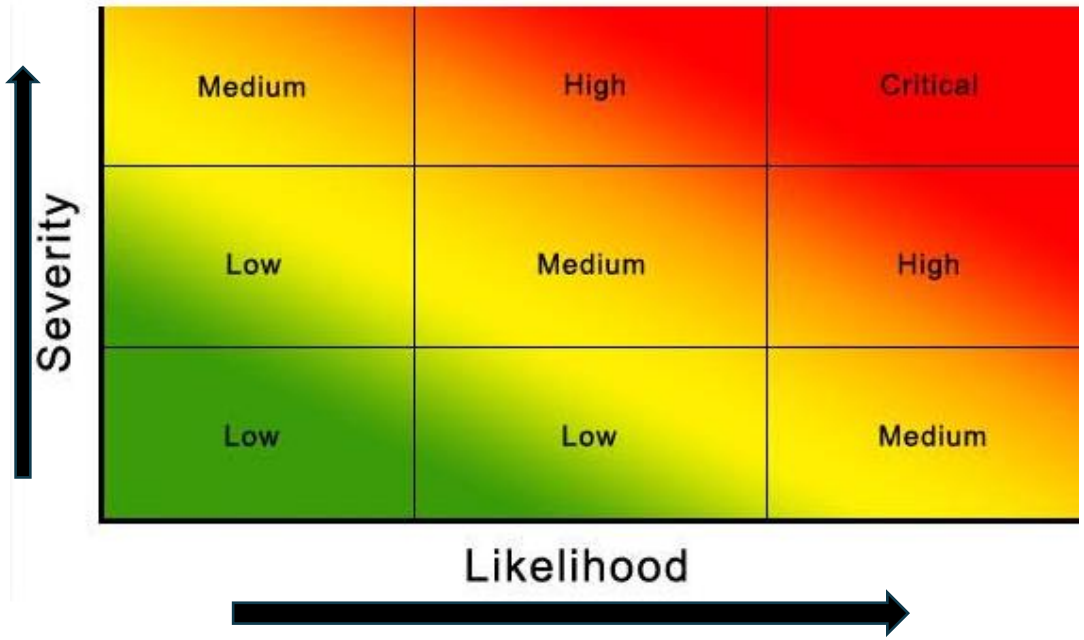
Step 3: Interviews

- C-Suite
- Board Members
- Medical Staff
- IT Leadership
- Privacy Officer
- HR
- Legal Counsel
- Operational leaders

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Heat Map / Prioritizing Risk

Heat Map



Prioritizing Risk

Not every risk deserves equal attention.

Focus on:

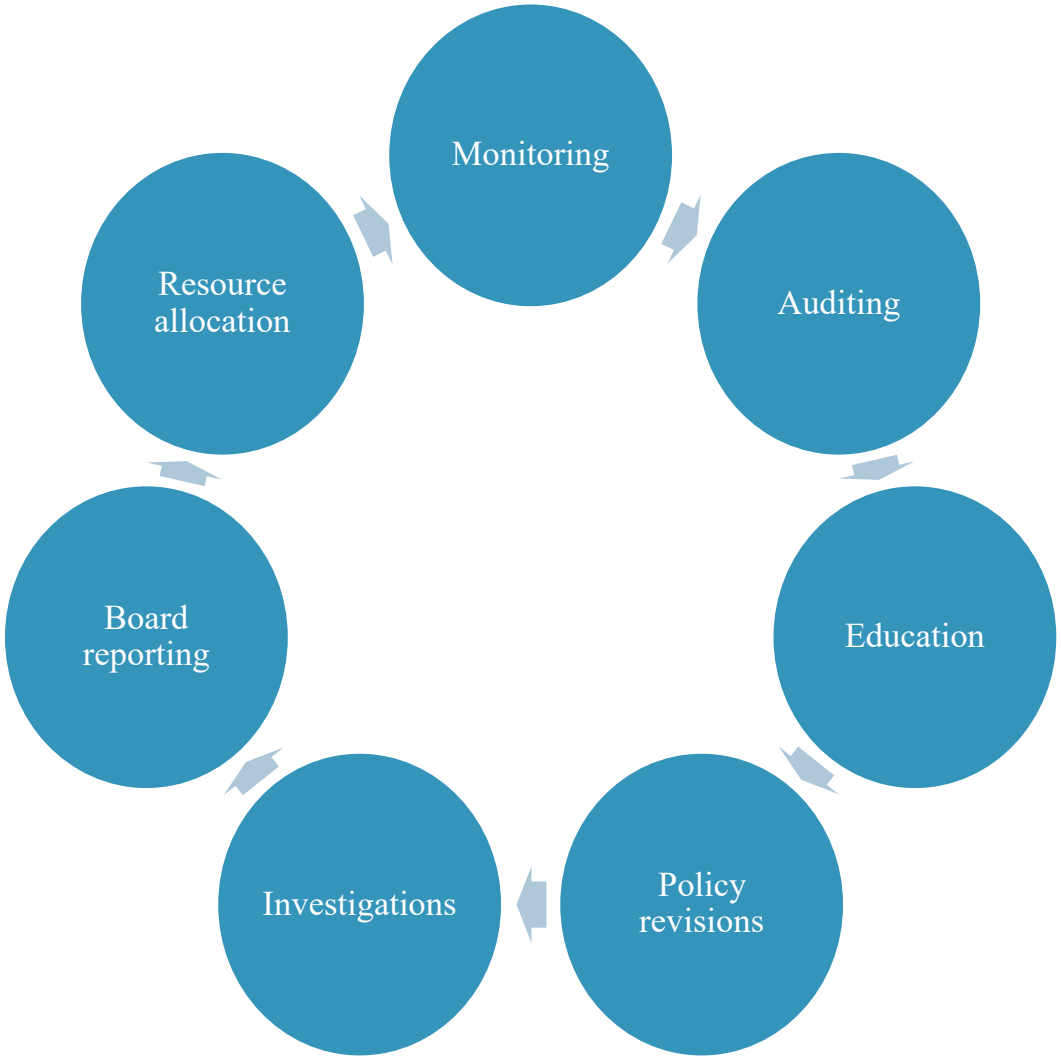
- Highest impact
- Highest likelihood
- Weakest controls
- New regulations
- Emerging technologies

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Building the Annual Compliance Work Plan

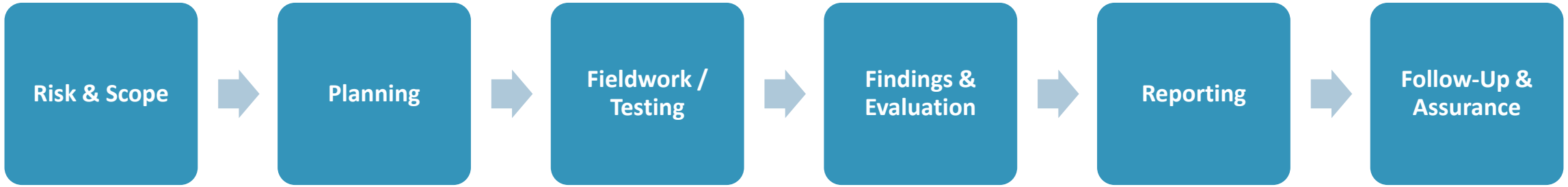
Risk assessment results drive:



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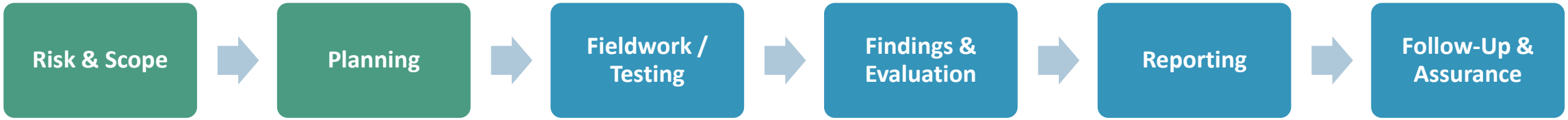
Anatomy of an Internal Audit



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Anatomy of an Internal Audit



Risk & Scope

- Define the audit objective
- Identify key risks, controls, regulations, and processes
- Establish scope, locations, departments, and period
- Determine materiality / risk level

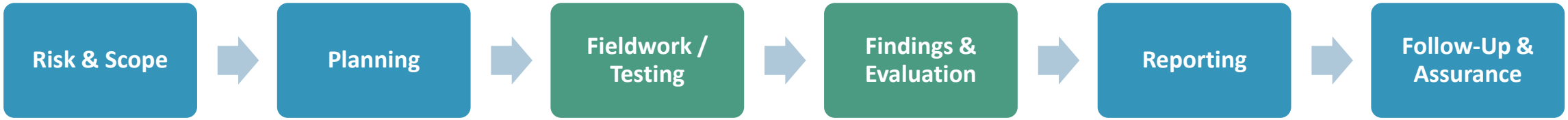
Planning

- Develop audit program and procedures
- Identify criteria: policies, regulations, standards, contracts
- Obtain process maps, prior audits, incident data, KPIs
- Determine sampling methodology

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Anatomy of an Internal Audit



Fieldwork / Testing

- Interviews & walkthroughs
- Document review
- Control design assessment
- Transaction / record testing
- Data analytics where appropriate

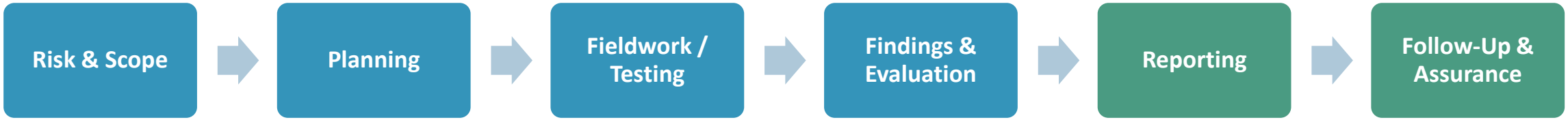
Finding & Evaluation

- Condition: What did we find?
- Criteria: What should have happened?
- Cause: Why did it happen?
- Effect/Risk: Why does it matter?
- Rate / prioritize the issue based on defined methodology

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Anatomy of an Internal Audit



Reporting

- Executive summary
- Findings and risk implications
- Management responses
- Corrective actions, owners & due dates
- Communication to appropriate governance committees

Follow-Up & Assurance

- Validate corrective actions
- Confirm remediation
- Track overdue actions
- Escalate unresolved high-risk issues
- Feed results back into the audit risk assessment

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Continuous Monitoring

Monitoring answers:

"Are controls working today?"



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Questions Internal Audit Should Ask

Is the risk assessment comprehensive?

Are resources aligned?

Do controls work?

Are corrective actions sustained?

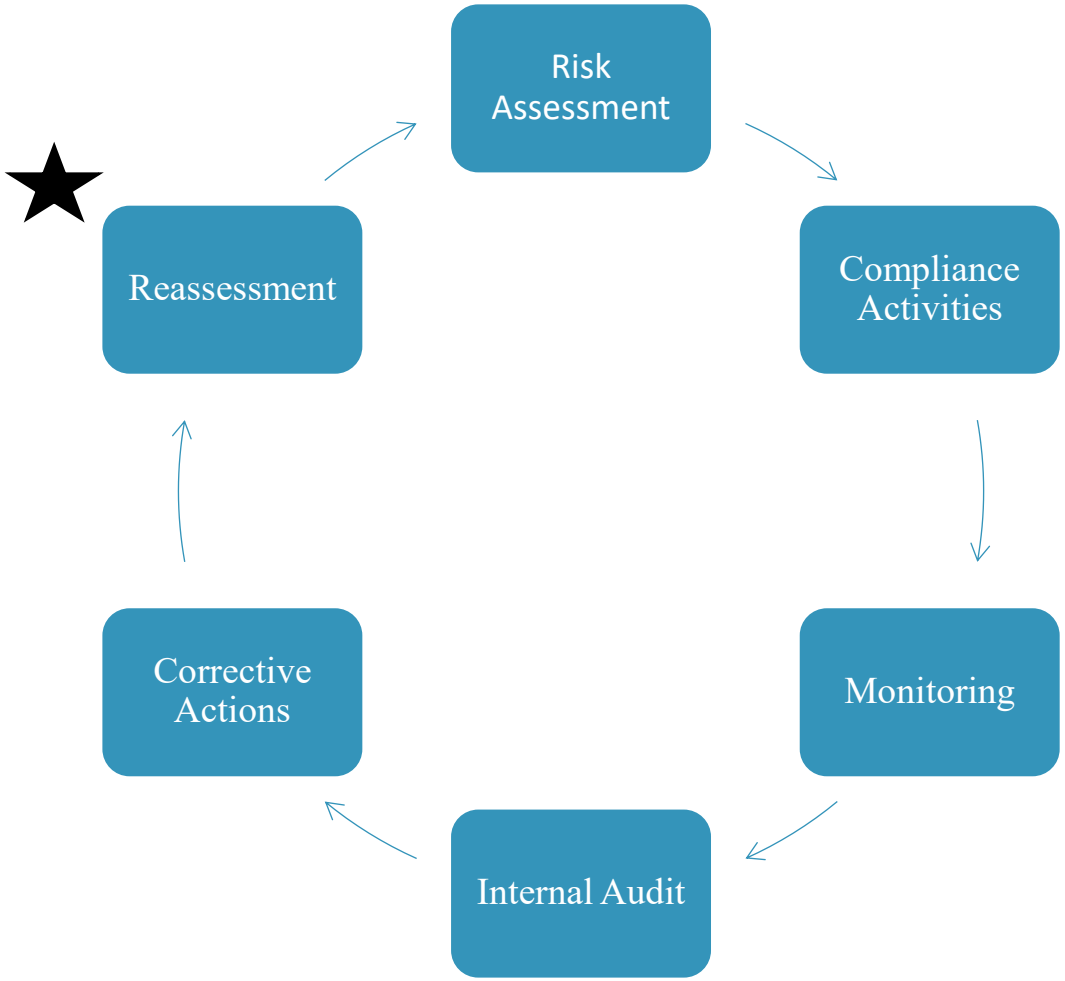
Are repeat findings decreasing?



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Compliance Program Effectiveness Cycle



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Comparison of Compliance & Internal Audit

Compliance

- Owns compliance program
- Monitoring
- Education
- Investigations
- Daily oversight

Internal Audit

- Independent assurance
- Auditing
- Validation
- Governance review
- Objective evaluation

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Common Pitfalls / Best Practices

Common Pitfalls

- Treating assessments as checklists
- Ignoring operational input
- Using outdated data
- Poor documentation
- No follow-up
- Failing to reassess
- Working in silos

Best Practices

- Use multiple data sources
- Interview leadership
- Leverage analytics
- Coordinate with ERM
- Document rationale
- Measure outcomes
- Report to leadership
- Repeat annually

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Key Takeaways

- Compliance begins with understanding risk.
- Risk assessments drive priorities.
- Effective compliance programs require continuous evaluation.
- Internal Audit provides valuable independent assurance.
- Together they strengthen governance and protect patients.

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Thank You

Questions?