

Enabling Business Performance: Innovations in Compliance Monitoring

Jonathan Mackenzie – *Managing Director, PwC*

David Durney – *Director, Abbott Laboratories*

Michelle Horton – *Principal, PwC*



During our time together, we will discuss...

1 Business transformation – Drivers of change

2 Integrated compliance – A strategic enabler

3 Abbott's IT transformation – A case study

4 Leading compliance monitoring practices

5 Key takeaways and questions

Challenging the status quo: Global trends driving change

“66% of CEOs see more threats than opportunities to their business.”

PwC’s 19th Annual Global CEO Survey

“68% of CEOs plan to implement a cost-reduction initiative in the next 12 months.”

PwC’s 2016 Risk in Review Study

“79% of CEOs indicate that over-regulation is the greatest threat to their organization’s growth prospects.”

PwC’s 19th Annual Global CEO Survey

“51% of CEOs are making significant changes in how they use technology to assess and deliver on wider stakeholder expectations.”

PwC’s 19th Annual Global CEO Survey

“68% of CEOs are entering into a new strategic alliance or joint venture in the next 12 months.”

PwC’s 19th Annual Global CEO Survey

“Globalization, economic realignment, and rapid technological change are likely to drive volatility for years to come.”

Growing Your Business: Risk Resilience, 2015

“Despite the various uncertainties shadowing the global economy, overall survey respondents express real optimism about growth: 75% expect an increase in revenue over the next two years.”

PwC’s 2016 Risk in Review Study

Challenging the status quo: Global trends driving change

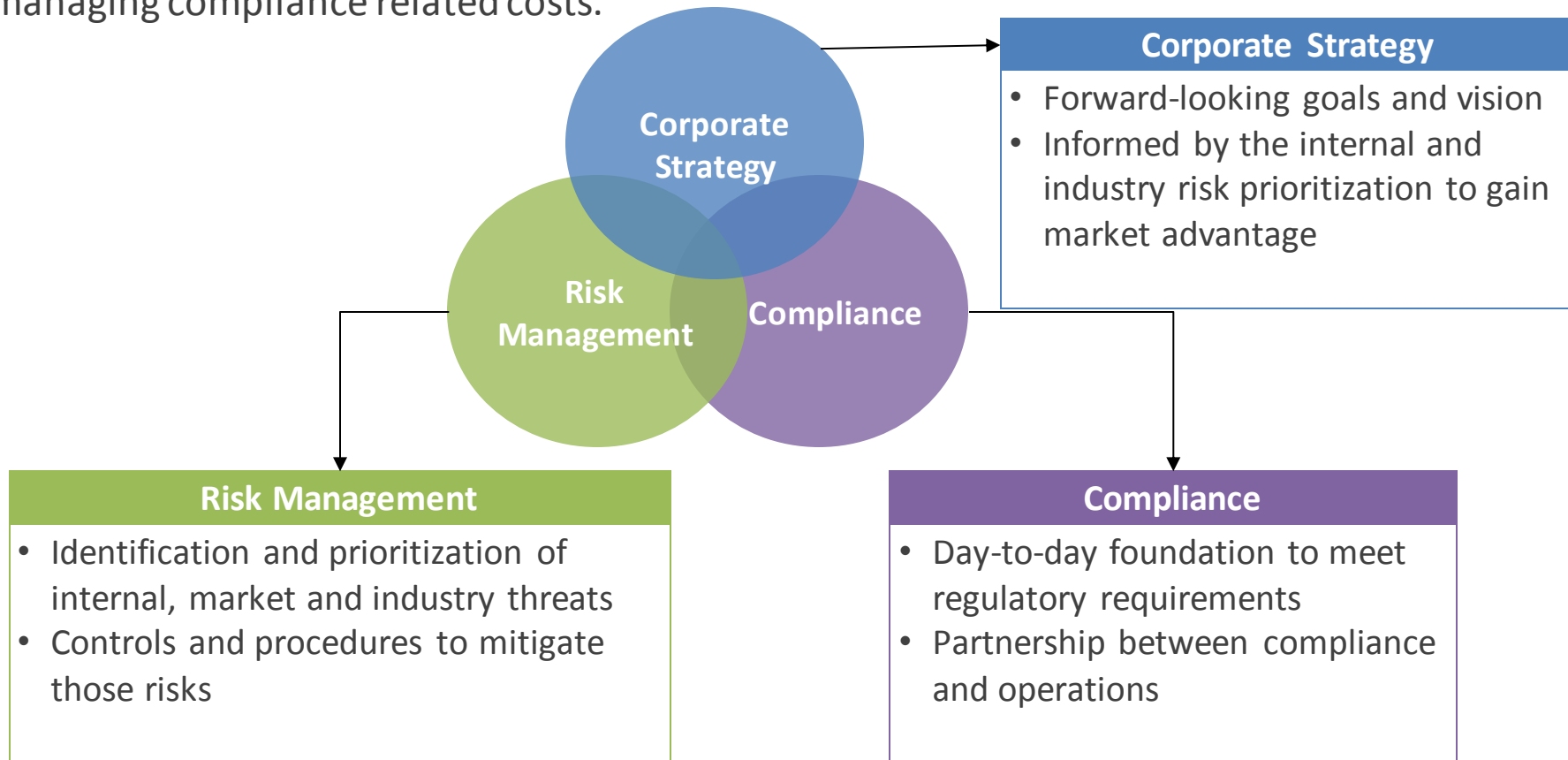
Changes in the global economy present new strategic opportunities and present new and evolving risks



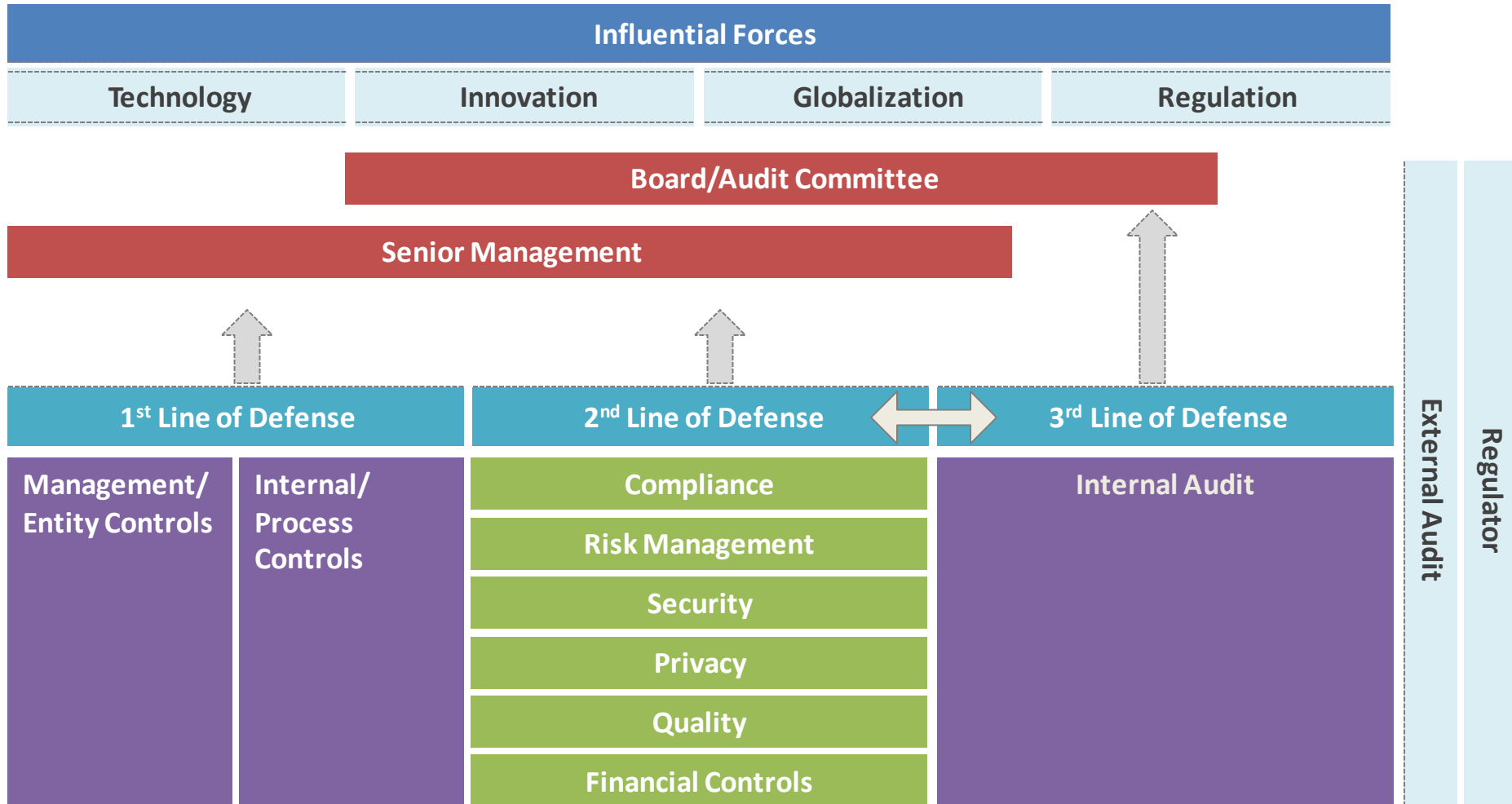
PwC's 2015 State of Compliance Survey

Compliance as a strategic enabler

As a strategic partner, corporate compliance is evolving, getting closer to the business, and proactively identifying risks. This evolution requires all elements of the compliance program to quickly respond to change and enable business or strategic initiatives, while still managing compliance related costs.



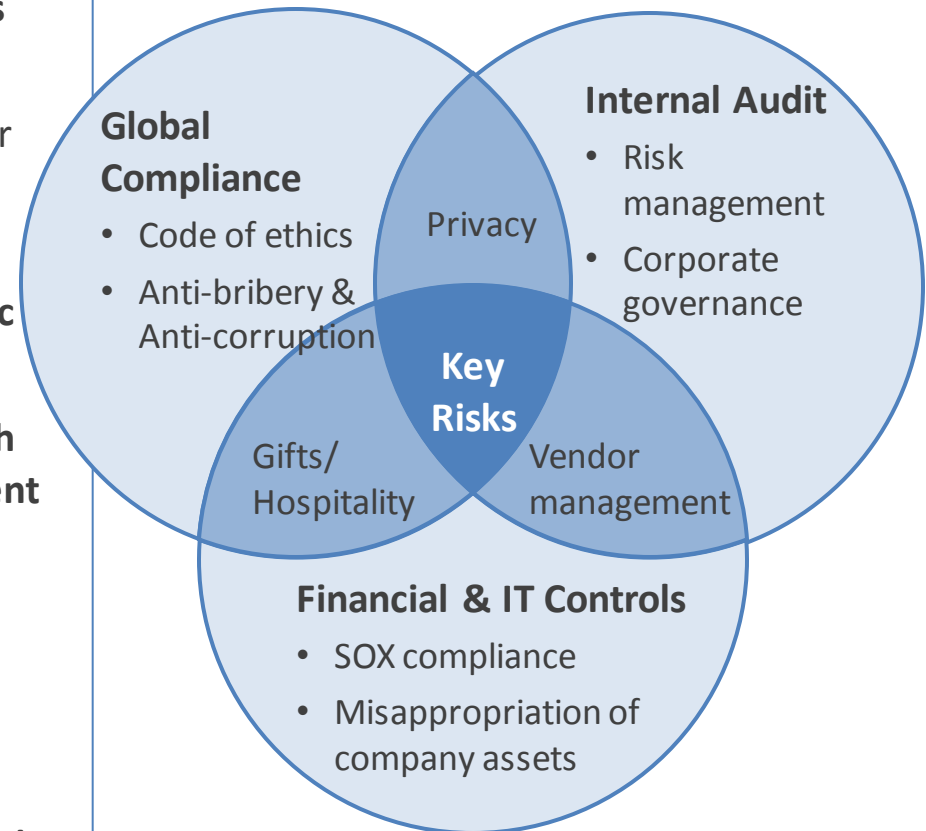
Assurance activities dispersed across the organization: Operating in silos



Assurance effectiveness: Does your program enable strategy?

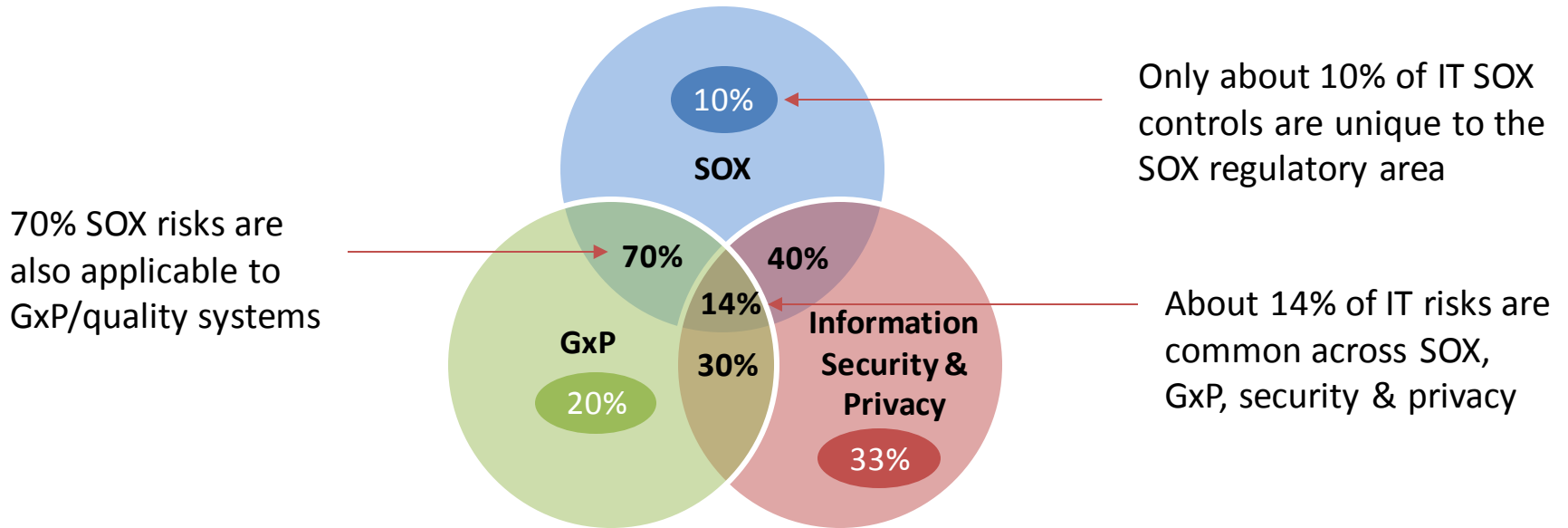
Leveraging monitoring insights to enable strategy and change

- ✓ Address compliance needs **before problems become systemic**
- ✓ Identify leading compliance practices and/or trends through the **execution of a consistent approach**
- ✓ Reduce cost of compliance through **strategic deployment of resources**
- ✓ Innovate compliance strategy to **evolve with continuously changing business/environment**
- ✓ Ensure **remediation is effective** to mitigate risk exposure
- ✓ **Consistent metrics, reporting, and communication** of the effectiveness of the compliance program throughout the organization, **to executive management, and to the board**



Illustrative example: The opportunity for change

Optimizing resource deployment and eliminating duplication - the graphic below represents the overlap that can exist across key IT risks in a pharmaceutical environment



Benefits of change

- Internal headcount savings and a sourcing model that can scale as systems are consolidated and as there are new ventures
- Reduced burden on business to support disparate and uncoordinated audit activities and remediation
- More comprehensive trending and root cause analysis to fix the problem across systems and regulatory compliance areas and limit repeat findings
- Proactive compliance monitoring approach provides for more predictable workload and helps to reduce the cost of non-compliance

Moving to an integrated model

Current State

GXP	SOX/CFR	Data Security	3 rd Party	Commercial Areas
<ul style="list-style-type: none"> • Electronic Records • Electronic Signatures • CSV 	<ul style="list-style-type: none"> • Access Control • Change Management • Operations 	<ul style="list-style-type: none"> • Privacy • Cybersecurity • MA201 	<ul style="list-style-type: none"> • Contract Compliance • Quality • Security 	<ul style="list-style-type: none"> • Safety • Privacy • OPDP
Corporate policies, procedures, processes, guidelines				
2 nd Line Monitoring	2 nd Line Monitoring	2 nd Line Monitoring	2 nd Line Monitoring	2 nd Line Monitoring

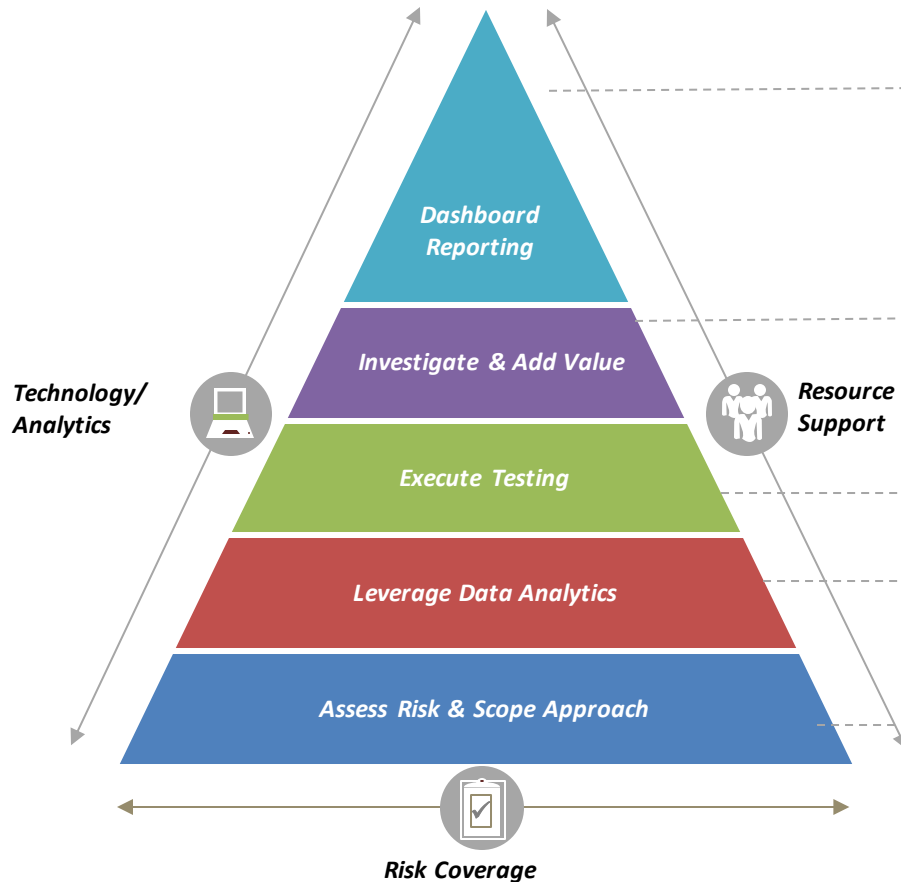
A compliance framework that integrates compliance/regulatory risks into a common set of objectives that can be applied across applications can minimize cost and organizational risk

Future State

GXP	SOX/CFR	Data Security	3 rd Party	Commercial Areas
<ul style="list-style-type: none"> • Electronic Records • Electronic Signatures • CSV 	<ul style="list-style-type: none"> • Access Control • Change Management • Operations 	<ul style="list-style-type: none"> • Privacy • Cybersecurity • MA201 	<ul style="list-style-type: none"> • Contract Compliance • Quality • Security 	<ul style="list-style-type: none"> • Safety • Privacy • OPDP
Corporate policies, procedures, processes, guidelines				
Integrated 2 nd line monitoring framework				
**Common Methodology **Common Framework **Common Tools **Scalable Offshore Resource Model				

Leading compliance monitoring practices

A monitoring program that is focused on key risks, leverages technology, and strategically deploys resources will enable strategic partnership and result in a more cost-effective model



Leading practices & benefits

Centralized, dynamic, timely

- Aggregated global testing results to provide both global and affiliate trending
- Dashboards for efficient analysis of testing results
- Consistent and regular communication tailored to key stakeholders

Efficient, effective

- Strategic deployment of skilled resources, allowing key personnel to focus on value-add activities (e.g. investigations, remediation, etc.)
- Implement methodology and integrate testing across functions to drive consistency and limit duplication
- Automate testing, where possible, to improve cost-effectiveness

Targeted, real-time, risk-based

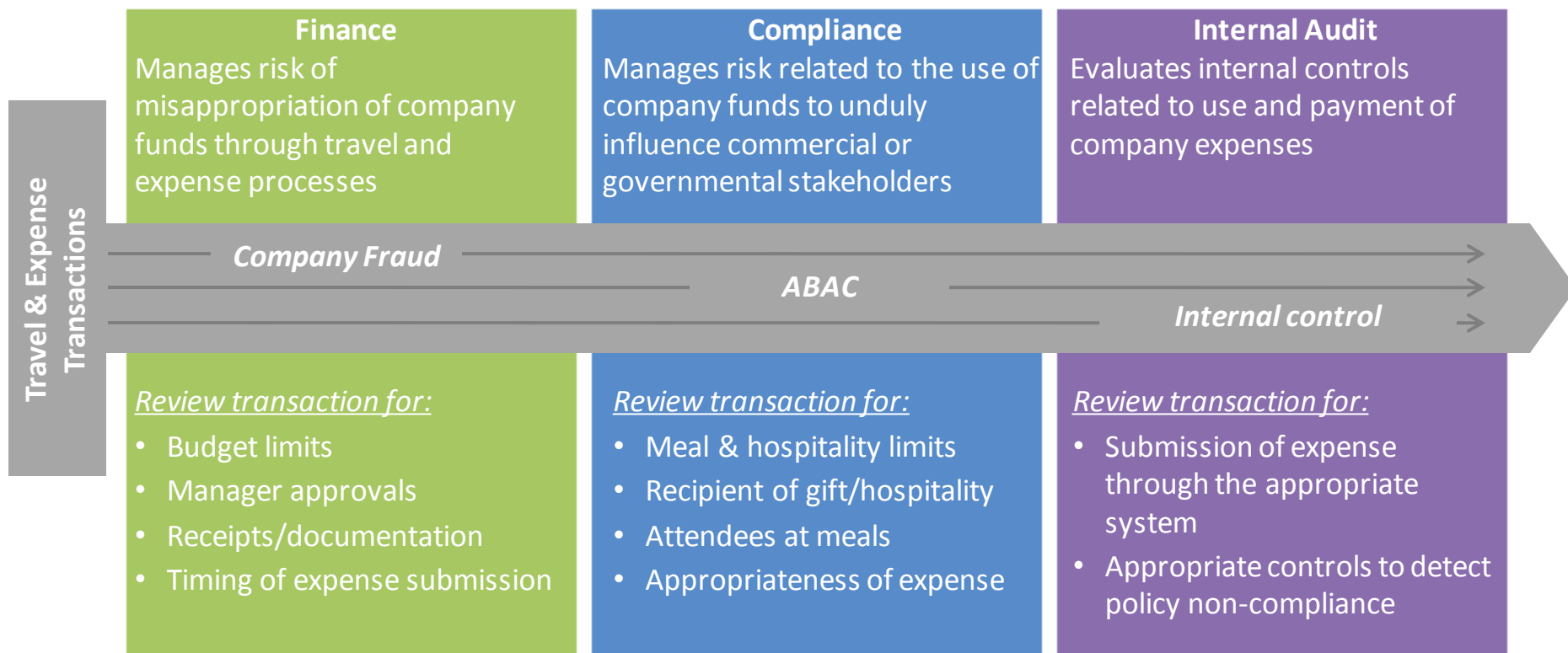
- Greater transactional coverage
- Efficient sample selection methodology
- Broad coverage across affiliates/functions

Continuous, flexible, consistent

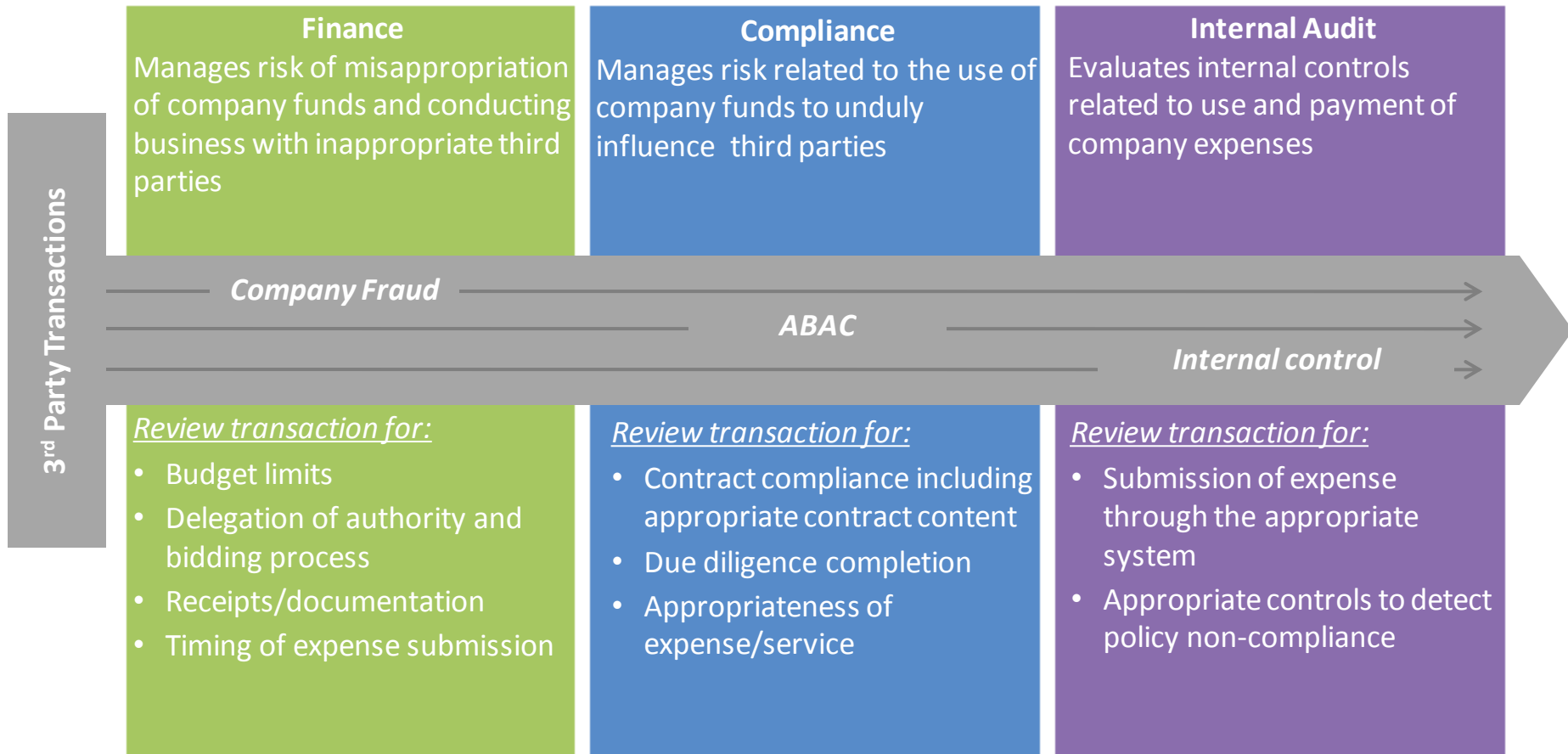
- Continuous evaluation of results driving future scope and approach
- Responsiveness to changes in activities, risk or business model
- Continuous assurance

Opportunities for an integrated approach: Travel & expense

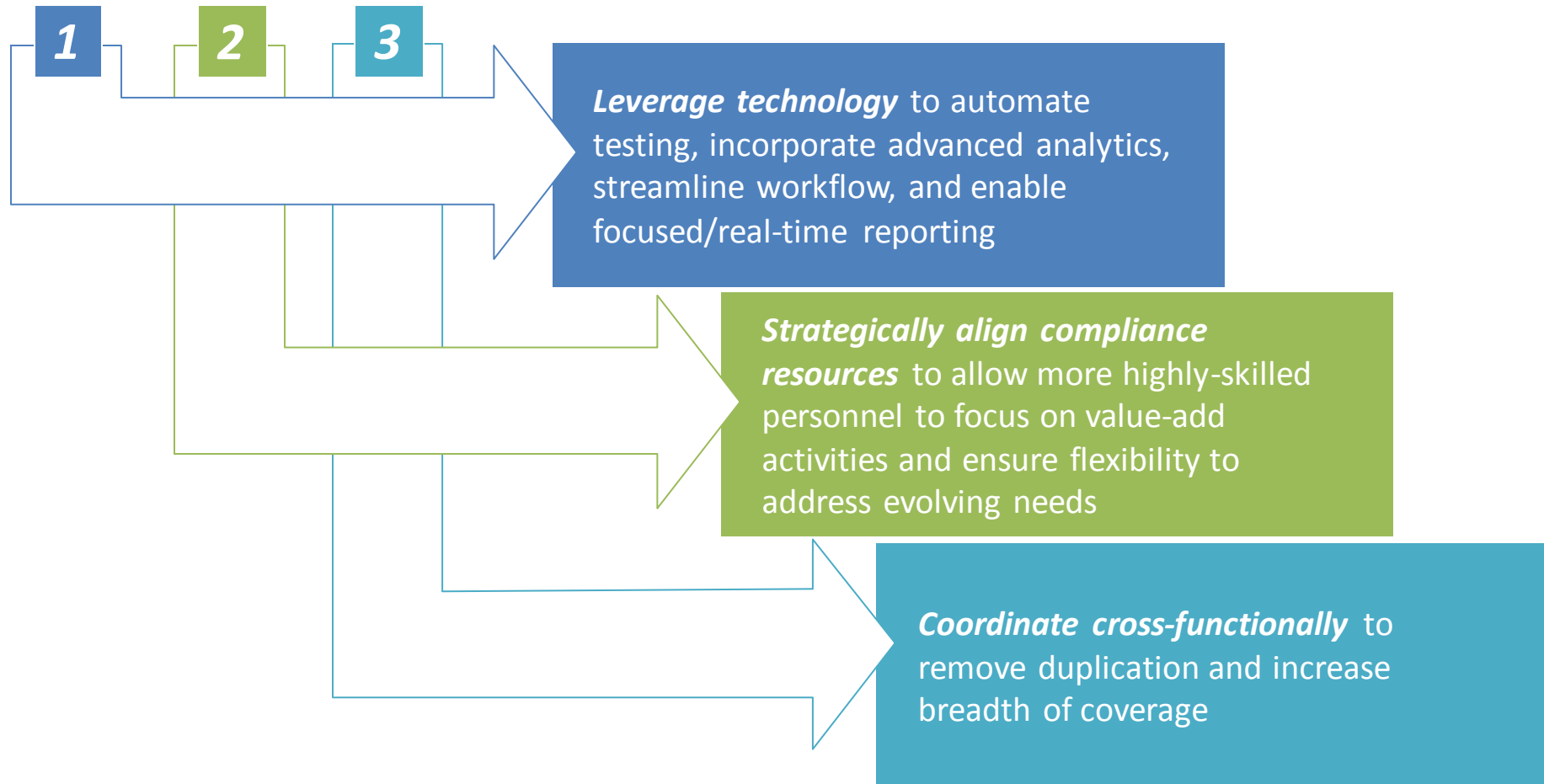
Companies have **numerous groups across the lines of the defense** with both **unique and interdependent risk management duties**. While the functions have distinct roles, there are activities for which multiple groups may **review the same event/transaction for related risks**. A coordinated monitoring approach can eliminate **duplicative** control testing across the various compliance areas.



Opportunities for an integrated approach: Third party management



Key takeaways



Questions?

Be sure to join the Twitter conversation: @CW_2016

Thank you

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