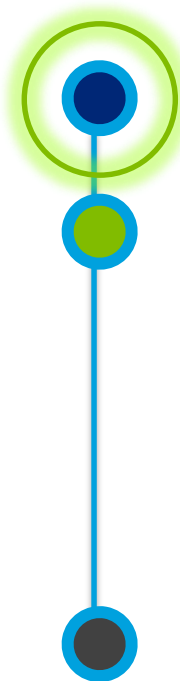




The challenge of compliance:
moving from cost to value

September 2016, Singapore

Agenda



Introduction

Compliance insights

1. Companies lack an enterprise-wide view of compliance risk
2. Big Data's role in compliance is often overlooked
3. The competitive advantage of an ethical culture is recognised
4. Mature compliance functions will help win the talent war
5. A lack of local compliance resource is a significant risk
6. Opportunities exist to optimise compliance effectiveness
7. Leading companies build regulatory engagement into their innovation models

Compliance future

Introduction to our 'challenge of compliance' research

The research was initiated in response to compliance becoming ever more important and complex for life sciences companies

The evolution of compliance – examples:



Increasing number of regulatory requirements which span multiple geographies, business activities and functions



New innovation is crossing into a world of regulatory uncertainty

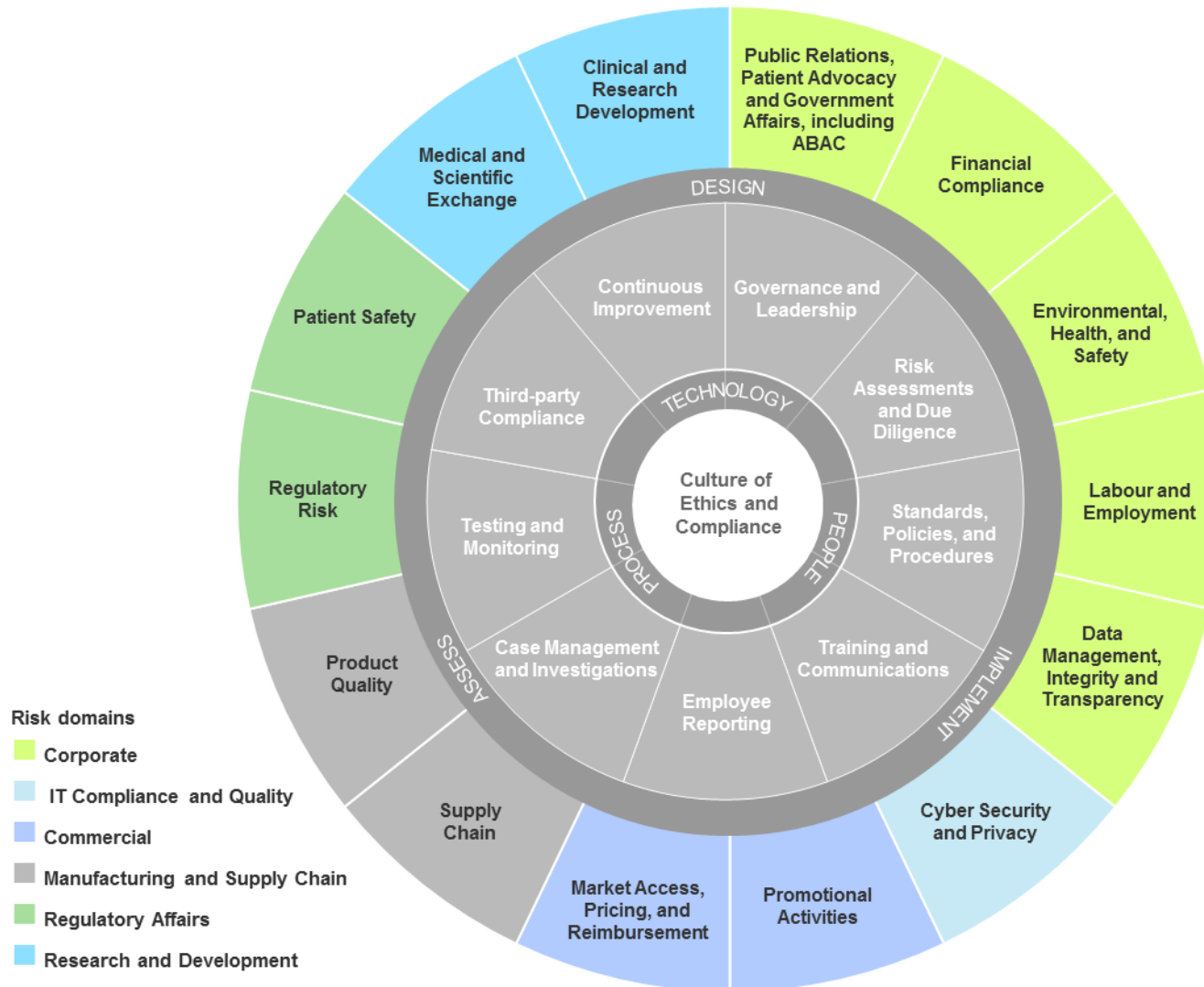


Compliance failures can be costly, both in terms of fines and reputational damage

- Identifying, analysing and mitigating compliance risks are essential in developing an effective compliance programme and ensuring the future sustainability of the life sciences industry

Compliance risk universe

The scope of the research was driven by the full compliance risk universe



Objectives and outcomes of wave 1

Our report presents initial research findings, based on the views of senior compliance leaders in the life sciences industry and Deloitte's own specialists

Objectives were to assess:

- how well the industry understands the totality of its compliance risks
- how compliance is managed and implemented within life sciences companies
- what the future of compliance looks like

Outcomes

- Interviews with 26 compliance leaders from 11 companies:

Amgen

Biogen

Merck & Co.

Sanofi

AstraZeneca

JnJ

Novo Nordisk

Smith & Nephew

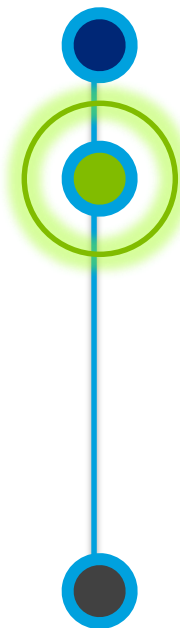
Baxter

Lundbeck

Roche

- 5 of these compliance leaders had quality or safety roles
- A second wave of research in being scoped to balance compliance risk area coverage and provide more benchmarking opportunities

Agenda



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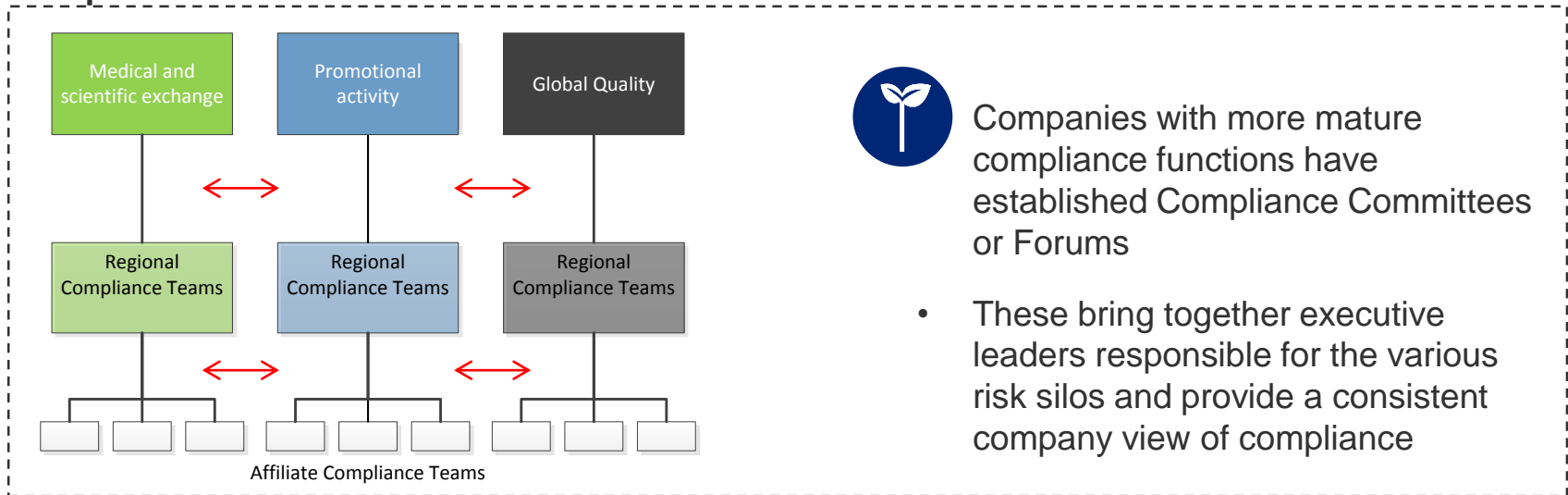
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Compliance future

1. Companies lack an enterprise-wide view of compliance risk

There should be a single 'owner' of compliance risk. This ownership could be vested in an individual or a compliance committee

Compliance risk siloes:



- Compliance risk is often addressed in discrete and separate domains
- But, compliance risk is becoming more interconnected
- Meaning most companies do not possess a full understanding of the compliance risk universe

2. Big Data's role in compliance is often overlooked

Opportunities exist for compliance to extract more value from data and future-proof their organisation but this requires a clear vision/ strategy which is often lacking

Agreement that current reporting systems provide:

A comprehensive view of compliance	✓	47%
Real time compliance info	✓	25%
Drill-down capability	✓	19%

Barriers to use of analytics:

- complexity of legacy IT infrastructures means accessing data is an uphill struggle
- integrating and analysing data is even more problematic

"You need to know the guy who knows the system to get access to the data. We can't go in and get the data out."



Companies with more mature compliance functions are:

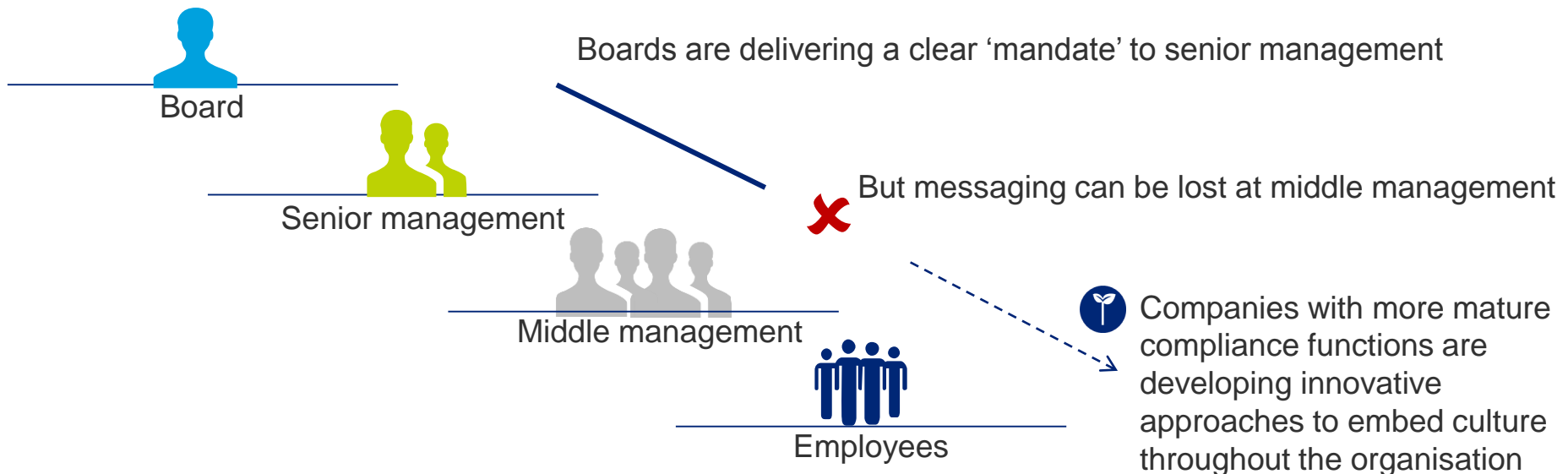
- building data warehouses and accessing via smartphones/tablets
- combining horizon scanning capabilities with data analytics to identify and mitigate new or emerging compliance risks.

3. The competitive advantage of an ethical culture is recognised

A strong and consistent compliance culture is key to enable a shift away from simple rules based compliance towards ethics and integrity



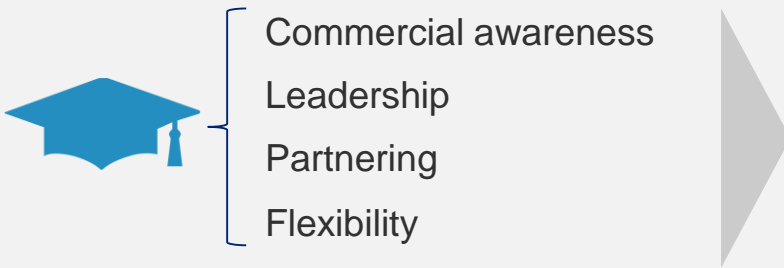
'Tone in the middle' is now at least as important as 'tone at the top'



4. Mature compliance functions will help win the talent war

Having a leading compliance reputation will attract talent across all areas of the business, not just in compliance

The compliance skillset is changing:



As compliance complexity within life sciences grows, the demand for high quality compliance resources will increase



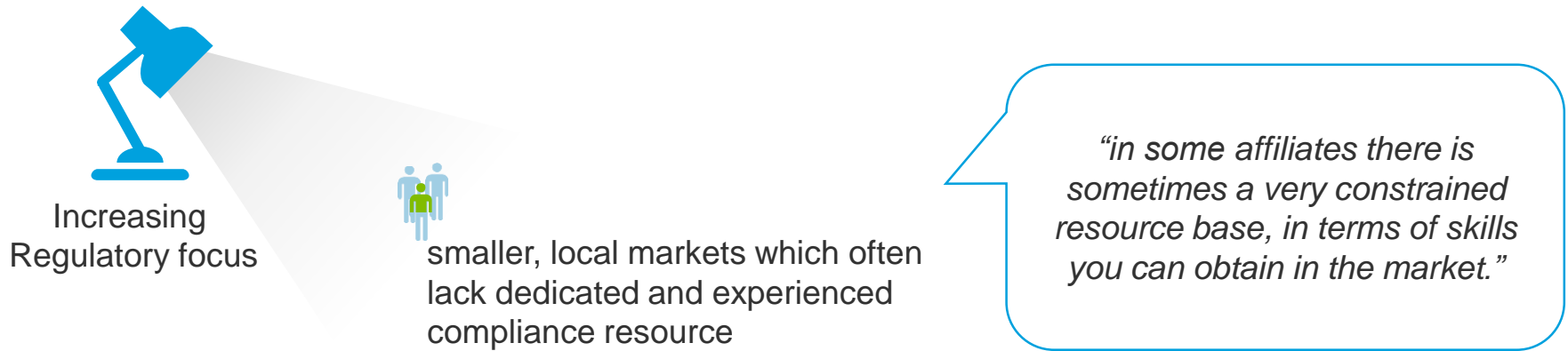
Companies with more mature compliance functions recognise compliance talent is key to improving effectiveness and are investing

- Investments in compliance talent will lead to a broader competitive advantage

“Attracting the best talent for a company that doesn’t have the best reputation for morals is a big disadvantage and many companies suffer from this. Having a very different profile where compliance is very high and your standards are very high can help”

5. A lack of local compliance resource is a significant risk

Compliance resources at the local level have not kept pace with incremental increases in local regulatory burdens – companies need to assess this risk

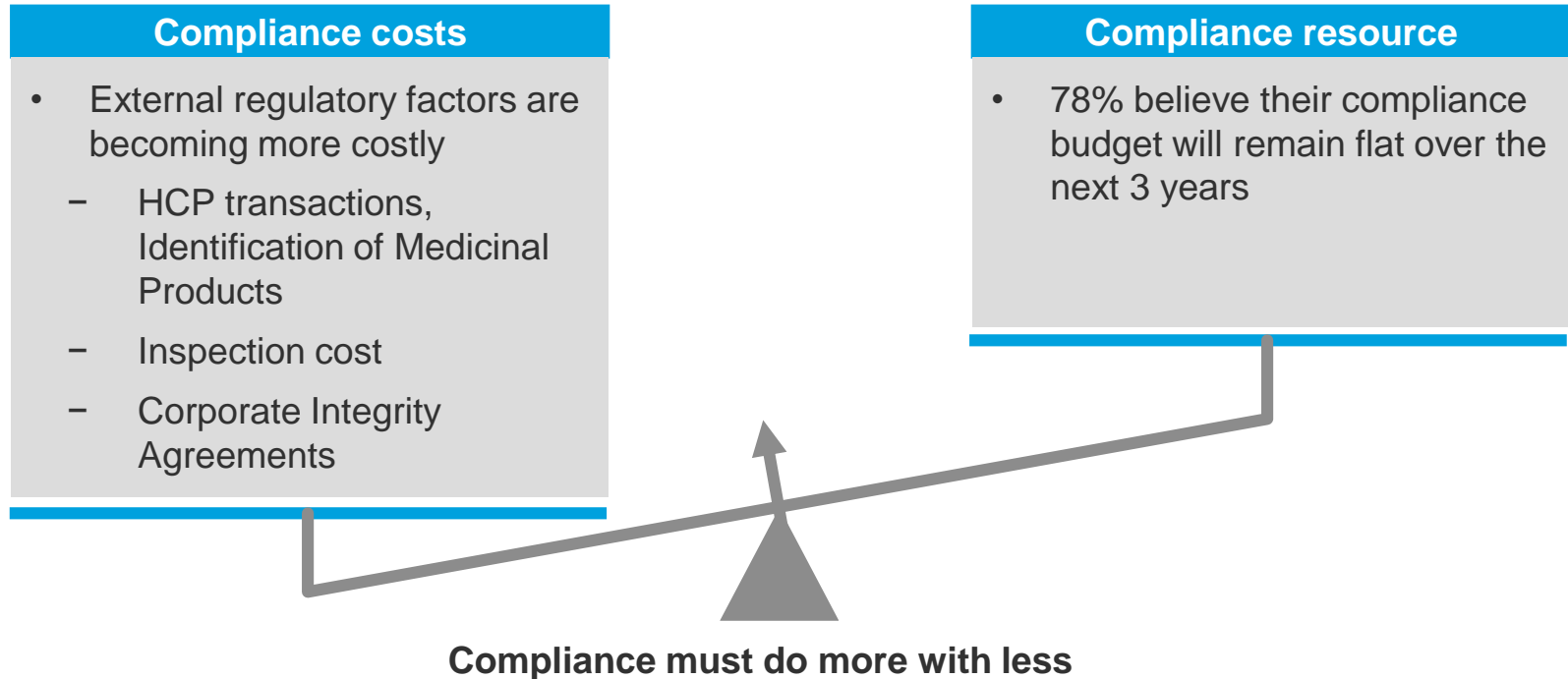


Companies with more mature compliance functions address this risk in one of two ways:

- creating ‘compliance excellence’ clusters among larger affiliates that smaller affiliates with limited compliance skills can consult
- bringing personnel from smaller, local affiliates into the global compliance function for training

6. Major opportunities exist to optimise compliance effectiveness and efficiency

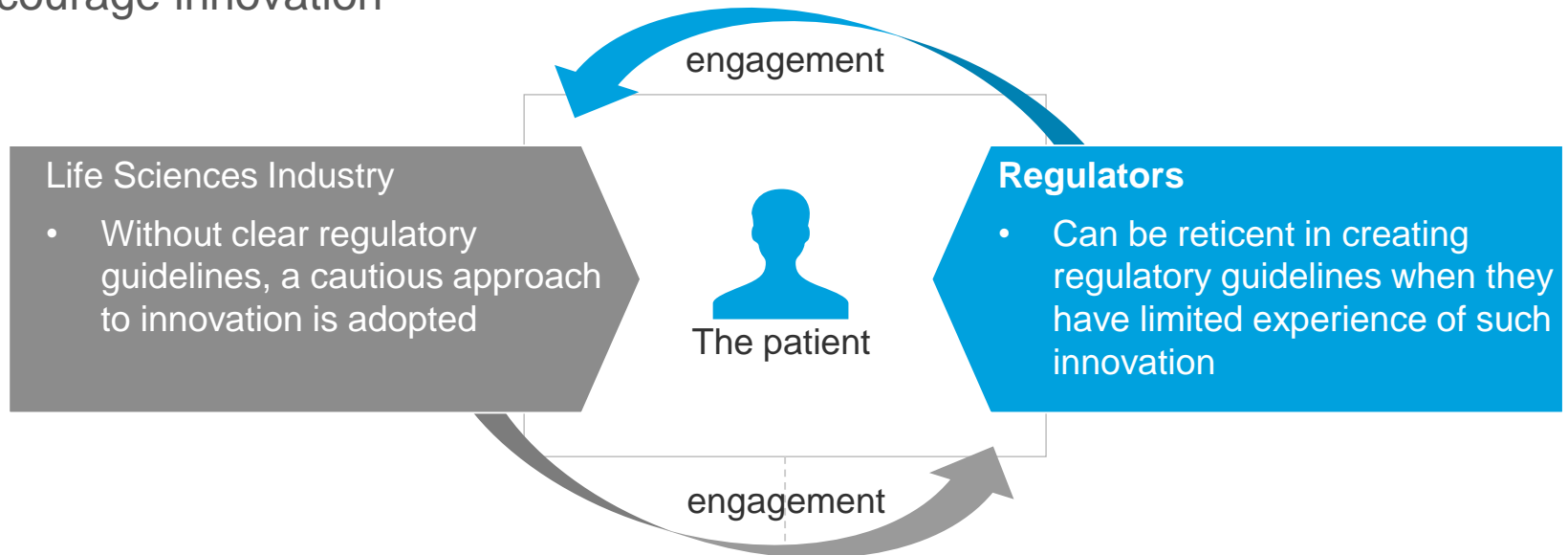
Improving the way compliance functions approach regulatory inspections and deploy risk mitigation tools/technologies will help them do more with less



Companies with more mature compliance functions are more able to create lean and sustainable processes allowing them to focus on and realise efficiencies within the compliance function. They also recognise the potential for compliance to become a competitive advantage

7. Leading companies build regulatory engagement into their innovation models

Regulators and industry are working actively with patients but in isolation, collaboration between all stakeholders will put patients at the centre and encourage innovation



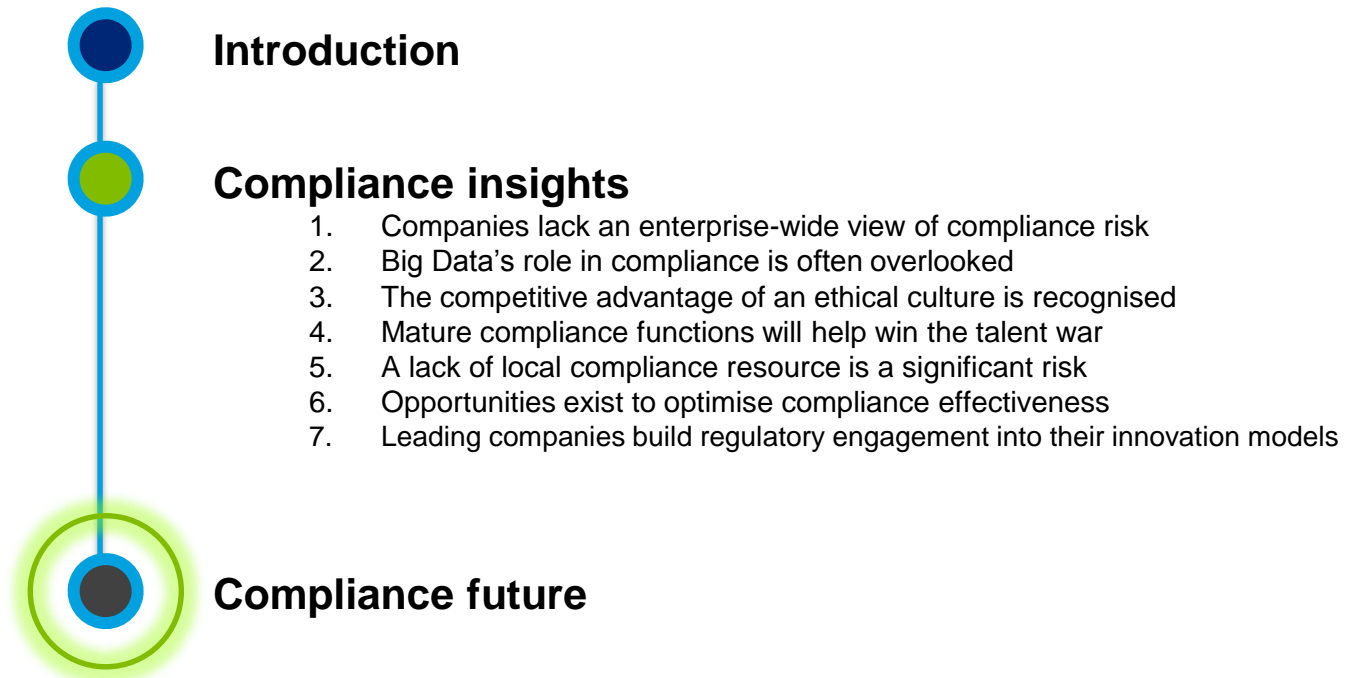
- The life sciences industry needs to take the initiative to negotiate a balanced position with regulators

- There is a pressing need for regulatory harmonisation whereby regulatory demands converge and reduce the burden on industry



Those at the forefront of compliance maturity have dedicated functions that represent organisational views on current compliance challenges as well as future innovation

Agenda



Compliance future

A conservative approach to compliance will not be sufficient for the future sustainability of the life sciences industry

Increasing regulatory complexity

Increasing regulator numbers

Changing nature of patient and social attitudes

Factors
impacting
compliance
ROI

Getting compliance right, from the outset, will clearly outweigh the negative impact of failing to implement compliance effectively

- **Innovation in compliance will become just as important in driving competitive advantage as innovation in other areas of the business**

“Compliance is a business hurdle, like access and pricing and talent; and mastering the skill of navigating compliance better than everyone else is a competitive advantage”



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