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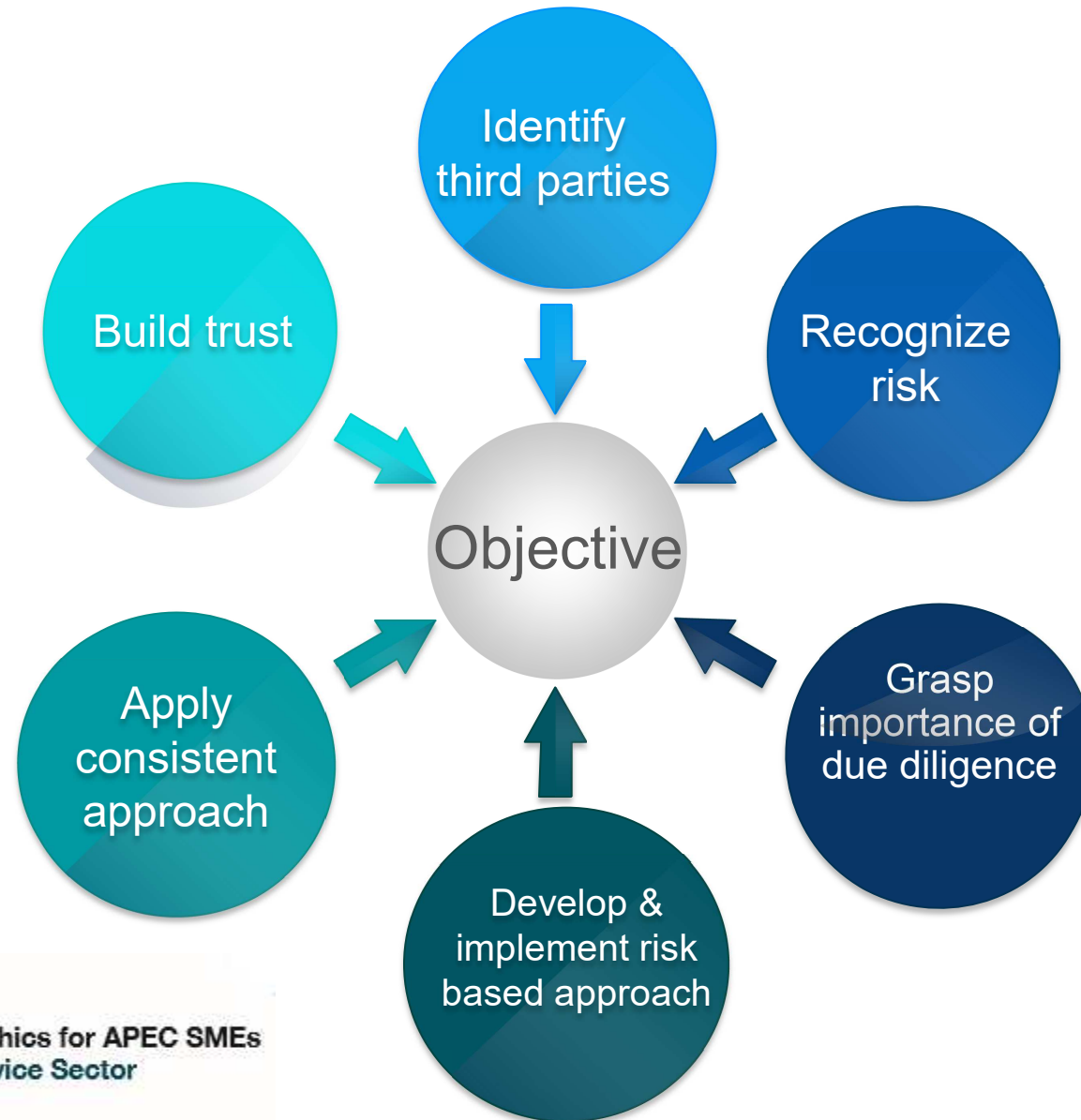
- Webinar Objective
- The Business Ethics for APEC SMEs Initiative and the APEC Kuala Lumpur Principles
- Mitigating Challenges and Risks
- Understanding the APEC Guidance for Ethical Third Party Intermediaries in the Medical Device Sector
- Guidance Implementation
- Questions and Answers

Objective of the Guidance



A Guidance that aims to strengthen ethical third party intermediary due diligence and inspires Small and Medium size Enterprises (SMEs) to engage in due diligence by creating achievable and manageable due diligence goals. The Guidance applies to the medical device company as well as the third party intermediary. Both are viewed by APEC as key actors in the medical device sector.

Learning Objectives



APEC



- APEC is the premier Asia-Pacific economic forum
- Asia-Pacific Economic Cooperation (APEC) operates as a cooperative, multilateral economic and trade forum
- Its primary goal is to support sustainable economic growth and prosperity in the Asia-Pacific region



**Business Ethics for APEC SMEs
Medical Device Sector**

Corruption
impedes
economic
stability



Business Ethics for APEC SMEs

Benefits APEC member economies	<p>Provides a platform for effective industry self-regulation</p> <p>Supports government enforcement and anti-corruption efforts</p>
Benefits businesses, especially resource-constrained SMEs	<p>Provides companies with clarity and harmonization in rules and practices</p> <p>Allows companies to compete across the region at a reduced cost</p> <p>In the case of the biopharmaceutical and medical device sectors, facilitates ongoing innovation</p>
Benefits patients (in the case of the biopharmaceutical and medical device sectors)	<p>Ethical collaborations fuel advances and promote access to life-saving medicines and technologies</p> <p>Ethical collaborations ensure that decisions are made in the best interest of patients</p>

Business Ethics for APEC SMEs Initiative

World's largest public-private partnership to strengthen ethical business practices in the medical device sector

More than doubled the number of medical device industry association codes

Trained over 1,500 stakeholders and expanded high-standards to 18,000+ companies (13,000+ SMEs)

Designed and implemented model consensus agreements to strengthen ethical business practices across health systems

The Kuala Lumpur Principles

Medical Device Sector Codes of Ethics

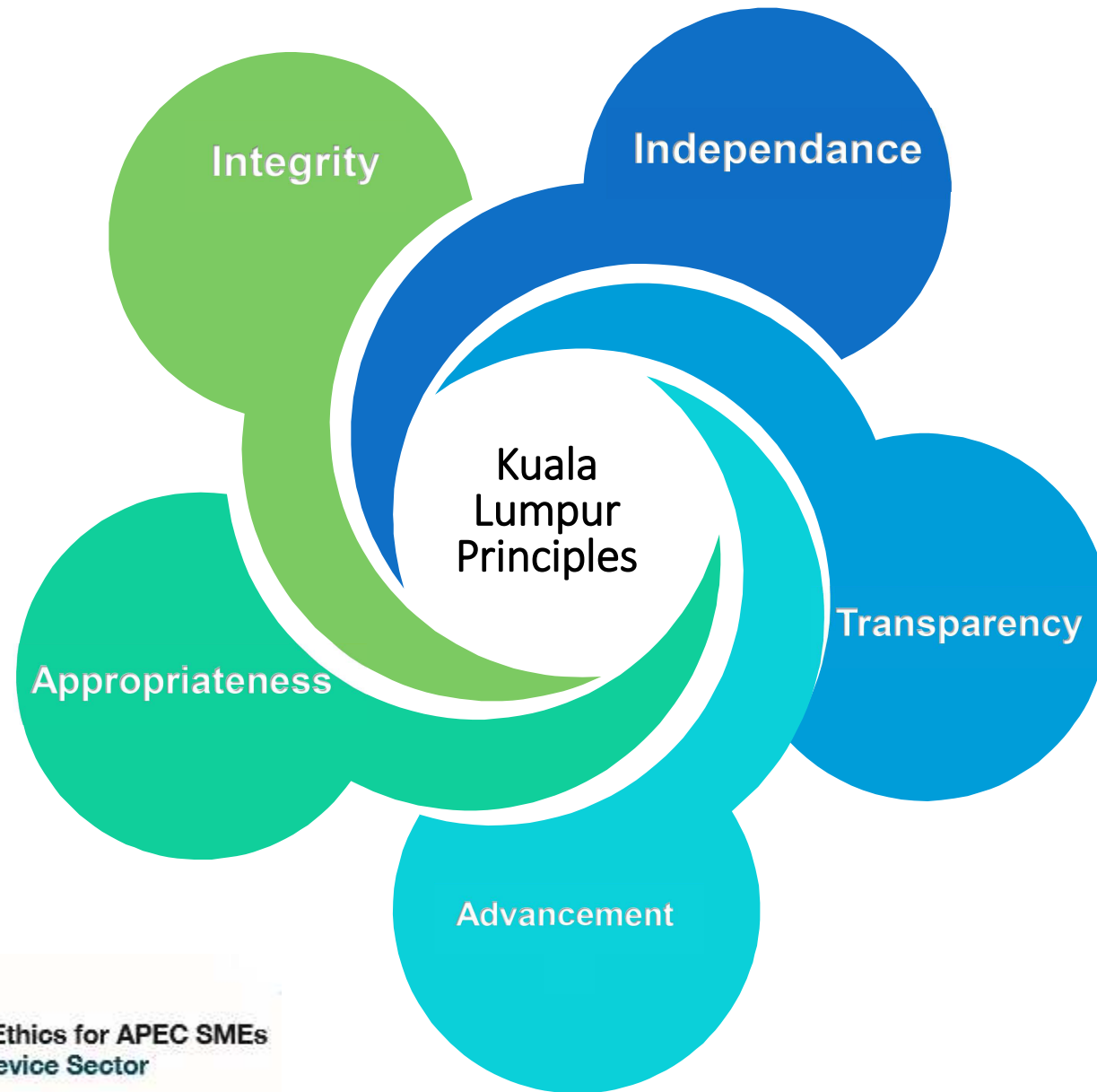
The APEC Kuala Lumpur Principles promote ethical interactions that:

- Promote appropriate interactions between the medical device companies and Healthcare Professional (“HCPs”).
- Enhance patient access to the safe and effective use of medical technologies
- Promote innovation and the ongoing development of advanced medical technologies
- Facilitate open and transparent business environments
- Ensure that medical decision-making is made in the best interest of the patient.



**Business Ethics for APEC SMEs
Medical Device Sector**

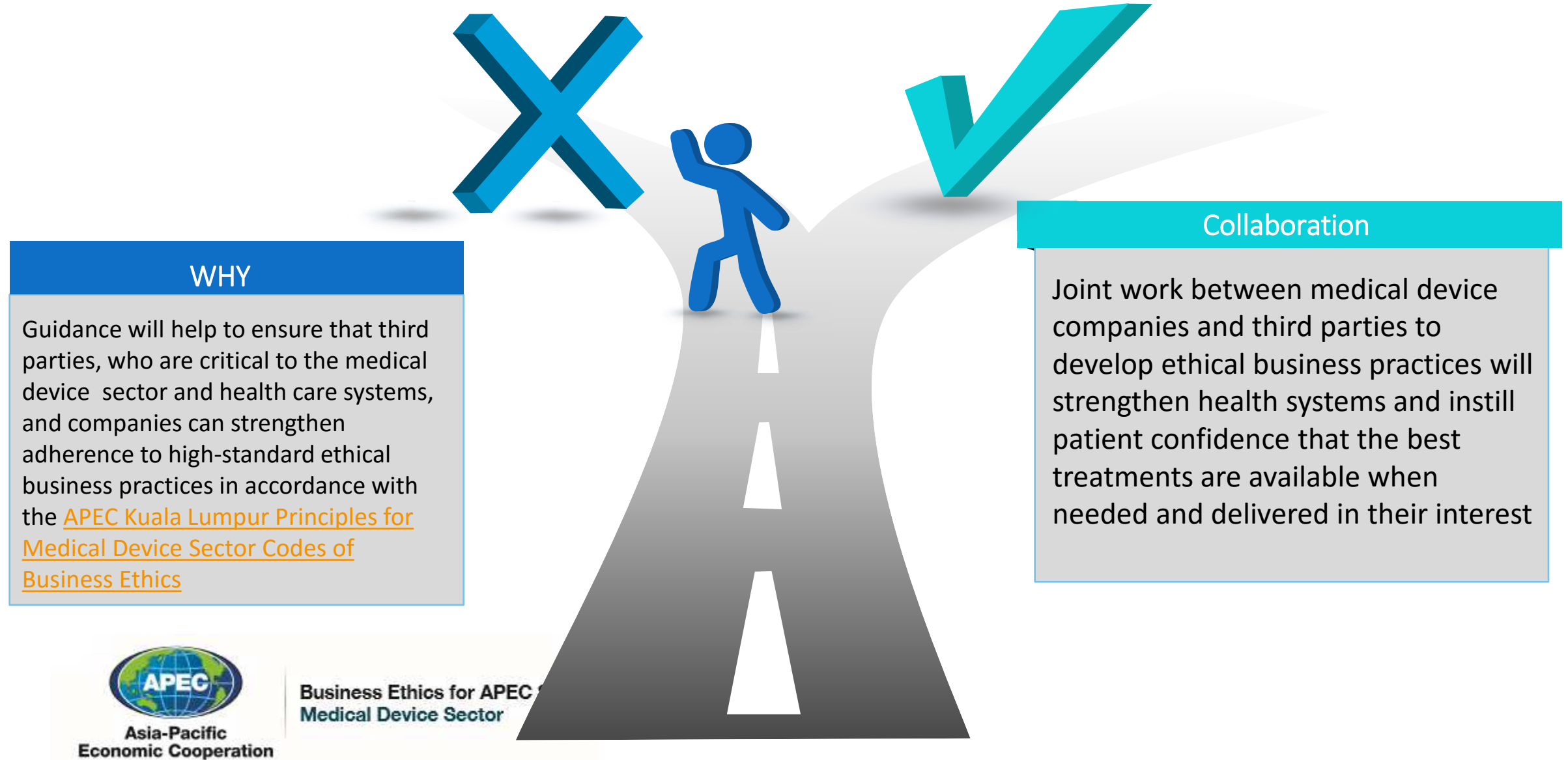
The Kuala Lumpur Principles





APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector

APEC Guidance for Ethical Third Party Intermediary Relationships



Why manage Third Party Relationships

Protect

- Protect your organization from risk and damage

Comply

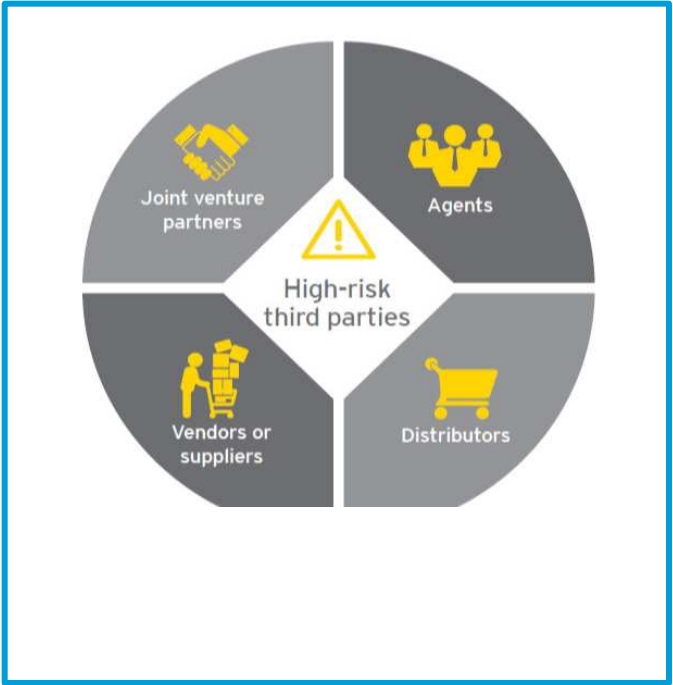
- Comply with laws and regulations

Create

- Create a culture of trust and transparency

INCREASING EXPECTATIONS: What the regulator is looking at ...

While regulators may have different priorities and focus areas when it comes to anti-corruption compliance and third party management there are a number of commonalities.



Re-catagorizing Risk over time



Careful consideration and Sound decisions



Process of continual monitoring



Consistently applied approach



What is Third Party Risk Management and Third Party Due Diligence?

Third Party Risk Management

- Refers to all activities related to your third parties, including risk ranking, screening data collection, documentation and ongoing monitoring

Third Party Due Diligence

- Refers to the assessment of third parties and their principals before and during an engagement



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The Meaning of the Guidance in Context

Codes of Ethics and Compliance programs should include the following elements:

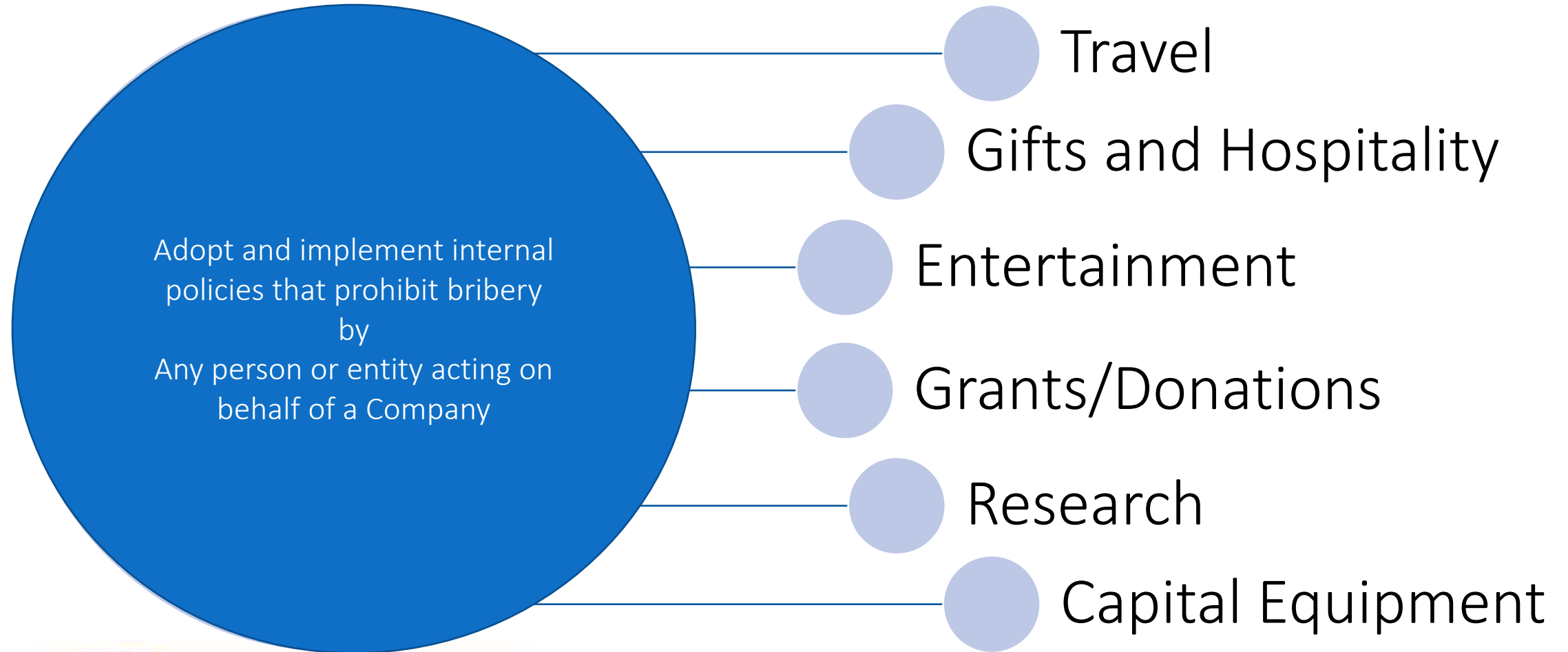


1. Written Anti-Bribery Policy/Procedures
2. Risk Assessments
3. Diligence Programs
4. Written Contracts
5. Training and Education Programs
6. Routine Monitoring and Auditing
7. Reporting and Corrective Action



Written Anti-Bribery Policy
and Procedures

Anti-Bribery Policy & Procedures



Risk Assessment

Companies and Third Party SMIs should evaluate the risk profile for proposed and utilized Third Party SMI arrangements....



Companies should assess the local risks through:

Published corruption indices as well as specific risk profiles

International and local legal requirements

Information from Third Party SMLs for potentially unusual arrangements

Information available from public sources or employees





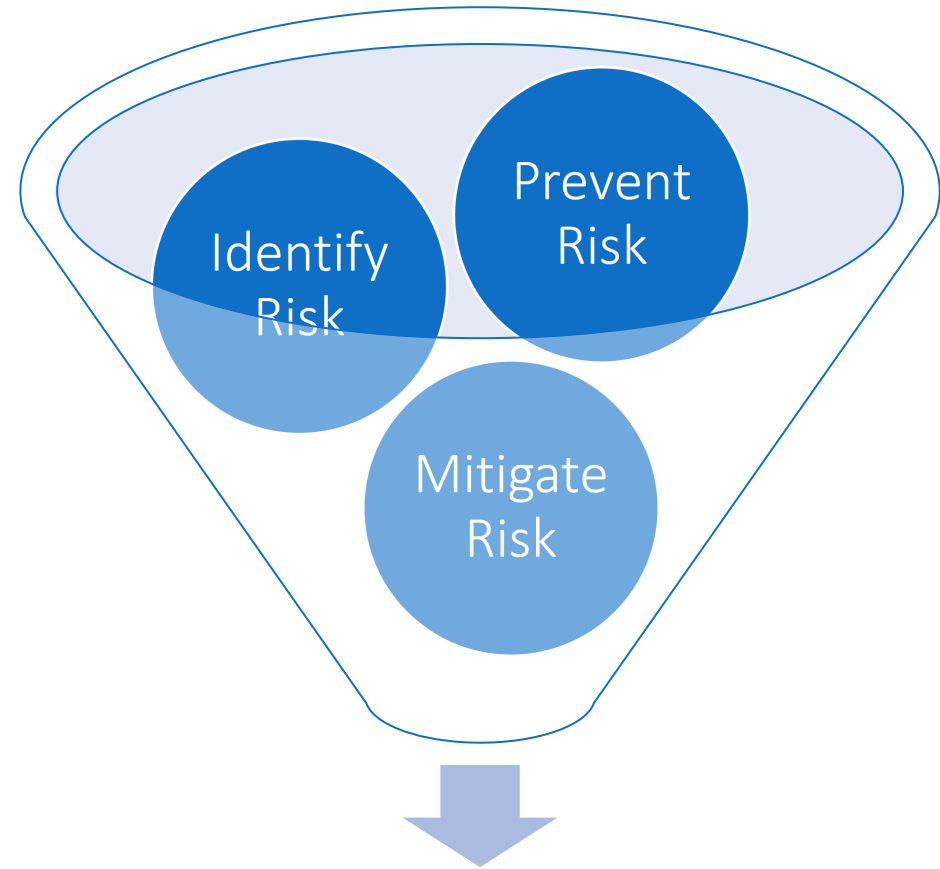
Third Party SMIs should:

- Support companies' risk assessments
- Assess and communicate international and local legal requirements
- Disclose potentially unusual arrangements; and
- Maintain accurate records for review

Diligence Program



Companies
and Third
Party SMLs
should
establish



Due Diligence Program



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Medical Device Sector



Written Contracts should include:

Due diligence

Compliance with international and local laws, ethical principles, and Company policies

Due diligence

The ability to conduct independent audits and monitoring, including access to relevant books and records

Due diligence

The ability to terminate an engagement for failure to comply with international and local laws, ethical principles, and Company policies; and

Due Diligence

Diligence rights upon renewal



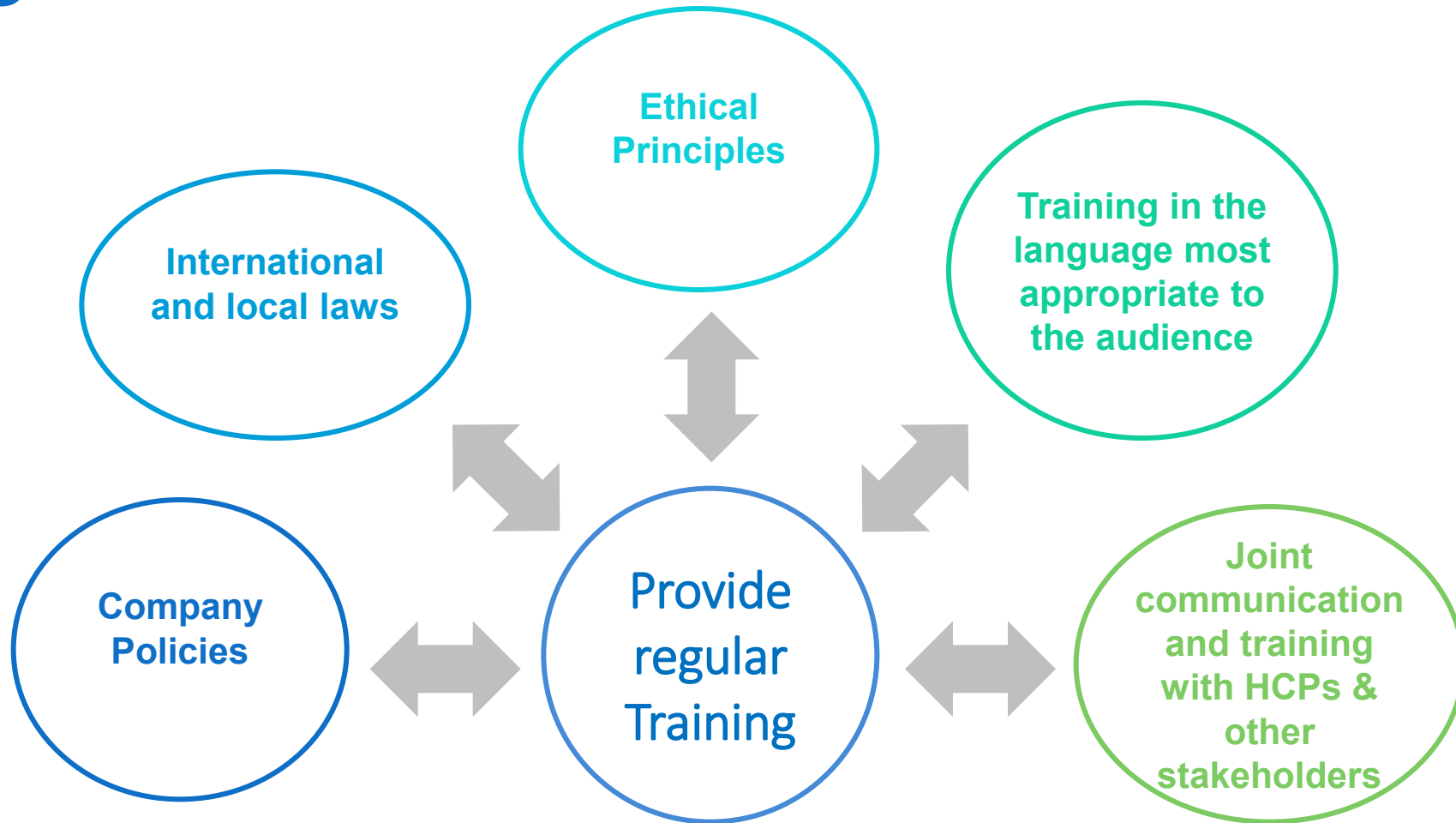
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Communication and Training



Training





Monitor and Audit

Periodic reviews and evaluations of the anti-corruption program



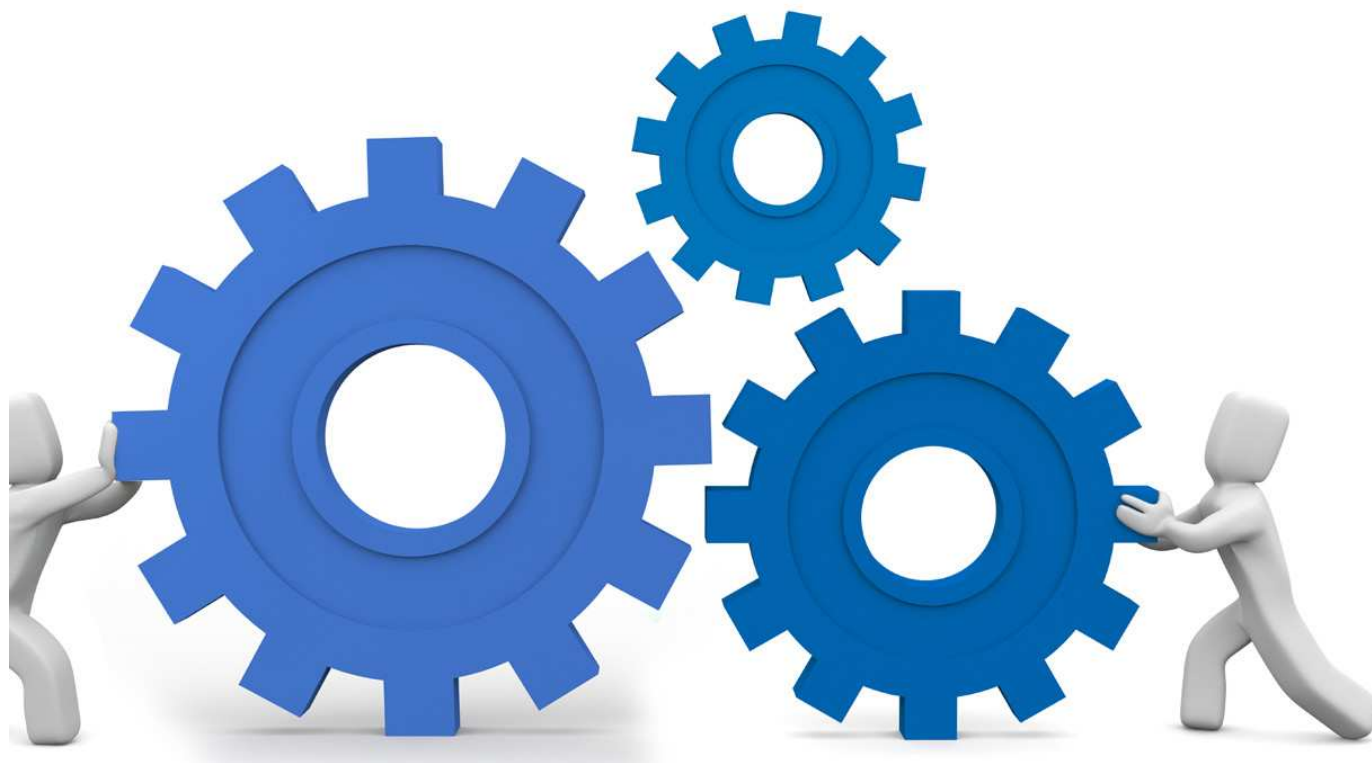
Corrective Action



Appropriate Corrective Action

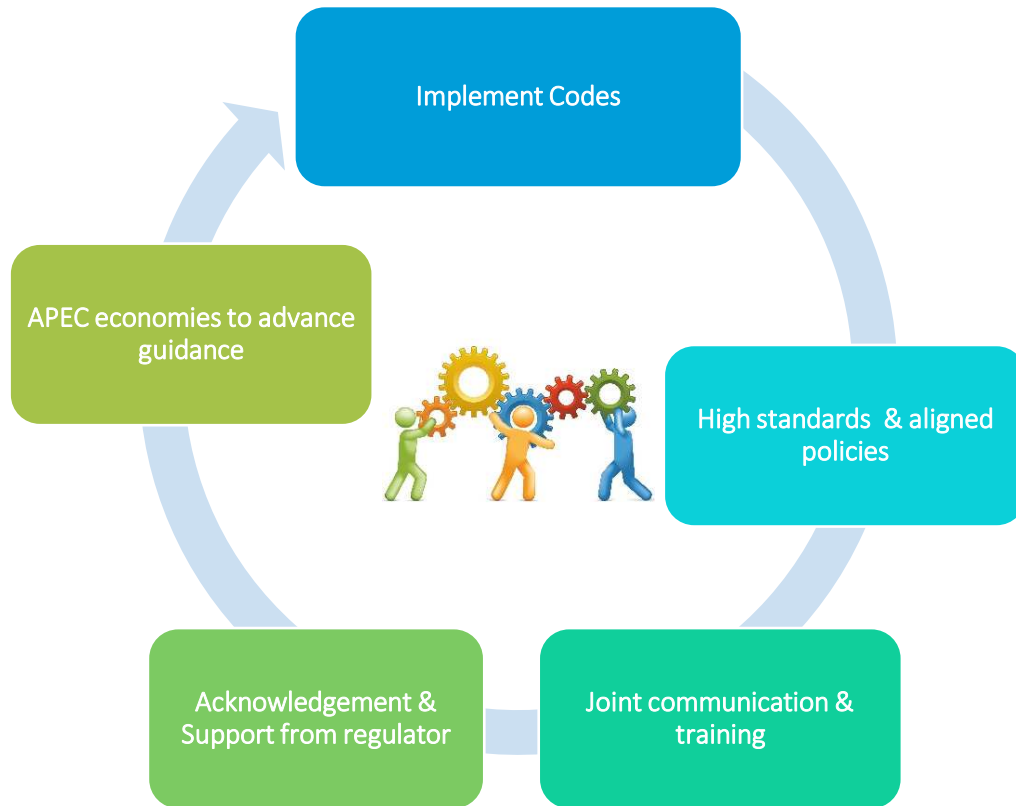
Corrective measures should be taken if either a Company or Third Party SMI representative fails to comply with:

- *international or local laws*
- *ethical principles*
- *company policies*
- *relevant contract terms or*
- *engages in other impermissible or unethical conduct*



IMPLEMENTATION

Actions for Implementation



Implement codes of ethics consistent with the principles set out in the guidance and take additional steps to encourage the adoption of this guidance among their respective members and /or employees

Encourage the development and implementation of high-standard, aligned policies and practices consistent with this guidance

Undertake joint communication and training on this guidance and other relevant policies

Encourage medical device sector regulators and enforcement authorities to acknowledge and support this guidance and to support steps by stakeholders to implement effective guidance for ethical Third Party SMI relationships

Engourage APEC economies to advance ethical collaborations consistent with this guidance through regular communication, joint policies, joint capacity building and other forms of collaboration

**“If you think compliance is expensive, try non-compliance”
- Former U.S. Deputy Attorney General Paul McNulty**

A very simple conclusion

Questions?

