

# Tactical Strategies in Negotiating with OIG in the Context of Investigations, CIAs, and Other Scenarios

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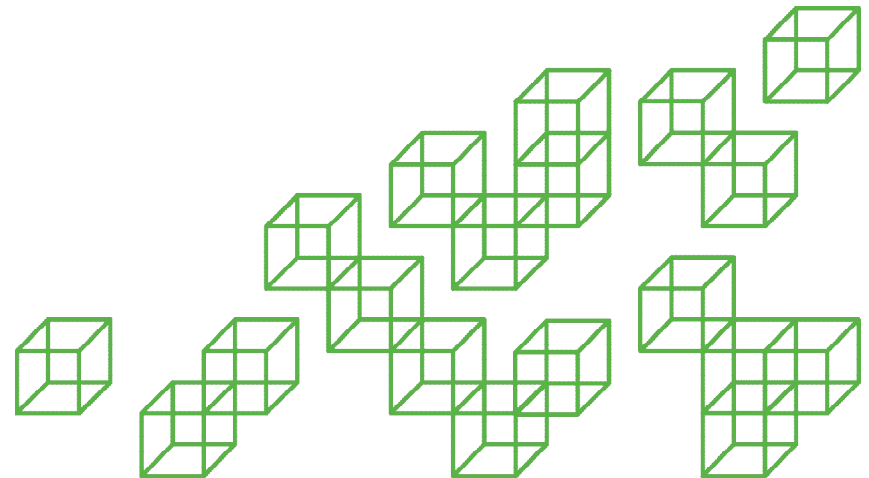
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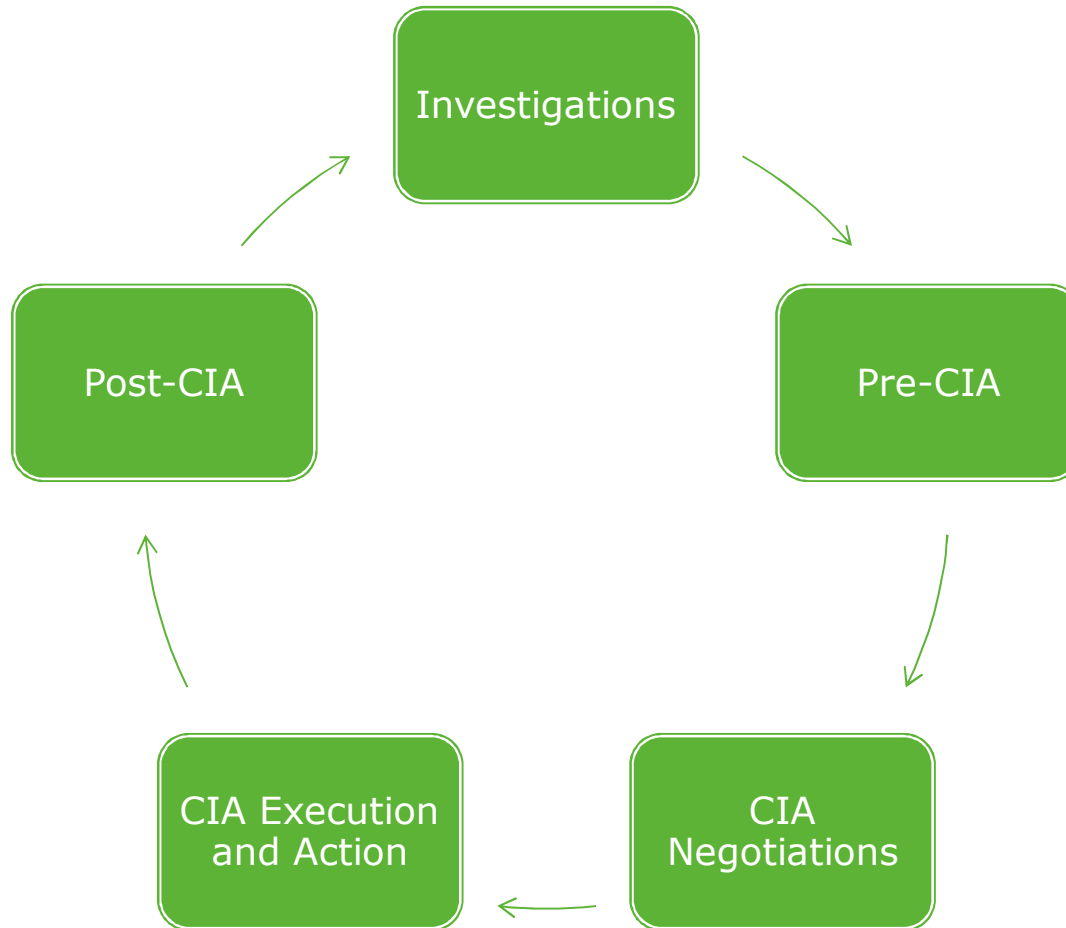
# Executive Summary

- Understand the link between the Department of Justice (DOJ) and Office of Inspector General (OIG)
- The interaction with OIG follows a cycle and reflects a long term relationship
- Understanding the operations of your company is just as important as understanding the legal facets
- Effective negotiation and implementation requires resourcing prior to initiation of OIG negotiations
- Companies dedicate Full-Time Equivalents (FTEs) to prepare, negotiate, and implement Corporate Integrity Agreements (CIAs) and also rely on external expertise/resources, particularly during the first two years of a CIA
- Certain scenarios, such as acquisitions, require significant preparation and coordination

# Understanding The Difference Between DOJ and OIG

- Prosecution vs. Compliance
- Can you manage the interaction between DOJ and OIG?
  - If so, what should you consider?
- The value of external counsel's operational experience
  - Understanding the law is half the equation
- Pharmaceutical/Medical Device company and OIG's interest can be aligned
  - OIG works towards the goal of mitigating harm to Federal Healthcare Programs and its beneficiaries

# Understand the Potential Cycle of OIG Interaction



# OIG Interaction: Pre-CIA

- Establish fundamental strategy
  - Exposure analysis, mock review, scenario planning
  - Probability of exclusion
    - ❖ Exclusion of company versus exclusion of individuals
  - What businesses/functions should be included and excluded from scope?
  - Will you get the typically 5-year term?
  - When should you ramp up remediation to meet typical CIA requirements?
  - Ability to meet time deadlines (e.g., to develop/refine policies and procedures)
  - Covered Person(s) definition
- Make sure your fundamental strategy can be supported by operational facts when discussing with OIG

## OIG Interaction: Pre-CIA (continued)

- Manage OIG expectations at the Management and the Board levels
  - What is their propensity for protracted negotiations?
  - Communicate drafts of CIA with stakeholders so you can get feedback based on operational realities
  - Establish and communicate needed budget and resources
- Establish and agree interaction principles with OIG
  - Transparency
  - Establish operational realities
  - Engage in regular dialog – not only when there is a problem
- Questions and strategy involving attorney-client privilege
- Selection and planning for the Independent Review Organization (IRO); discussion on the company's available resources / nature of operations / budgeting considerations

# OIG Interaction: During CIA

- Adhering to agreed-upon principles with OIG and vice versa
- Continue working with the business to perpetuate the understanding of obligations and update your understanding of changes in the business
- Handling reporting requirements
  - Changes in the business
  - Reportable Events
- Mock IRO, assessment of exposure, and communication plan
  - How should it change from year to year?
- Managing certification obligations and expectations; communicating changes in management
- OIG audits and inspections
- Working with IRO
  - Balancing the IRO and OIG relationship



# OIG Interaction: Post CIA

- Closing out the CIA
- Communication plans with OIG, DOJ, Food and Drug Administration (FDA)
- Closing assessment
  - What worked well? What did not work?
  - What processes need to be modified?
    - Escalation protocol, process, documentation, reporting
  - How has the business changed?
  - What do you still need and do not need?
  - Can you leverage Internal Audit and other groups to continue auditing and monitoring?
- How do you handle issues should they occur again?

# OIG Interaction: Other Scenarios

- Parallel matters with DOJ and OIG
- Internal investigations
- Acquisitions and due diligence